UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 06, 2023

IGM Biosciences, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39045**	**77-0349194**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
325 E. Middlefield Road Mountain View, California		**94043**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (650) 965-7873

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.01 per share	IGMS	The NASDAQ Global Select Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

As discussed in Item 8.01 of this Current Report on Form 8-K, IGM Biosciences, Inc. (the "Company") updated its corporate presentation and disclosed that the Company had an estimated cash and investments balance of $427.2 million as of December 31, 2022 (unaudited).

Item 8.01 Other Events.

The Company will participate in the 41st Annual J.P. Morgan Healthcare Conference in San Francisco, California from January 9-12, 2023.

A copy of the Company's updated corporate presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	**Description**
99.1	IGM Biosciences, Inc. Corporate Presentation
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: January 6, 2023

By: /s/ Misbah Tahir
Misbah Tahir
Chief Financial Officer

Exhibit 99.1

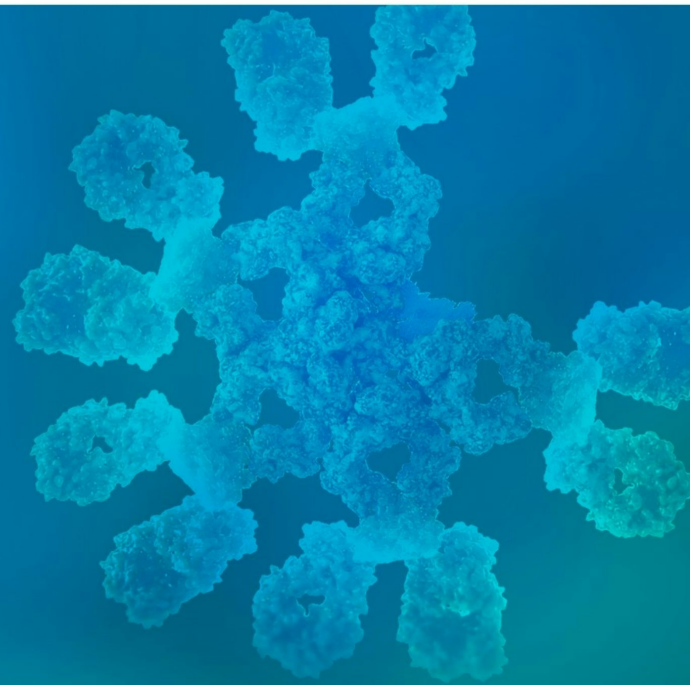
Global Leaders in IgM Antibodies

REIMAGINING

antibody medicines

Corporate Overview

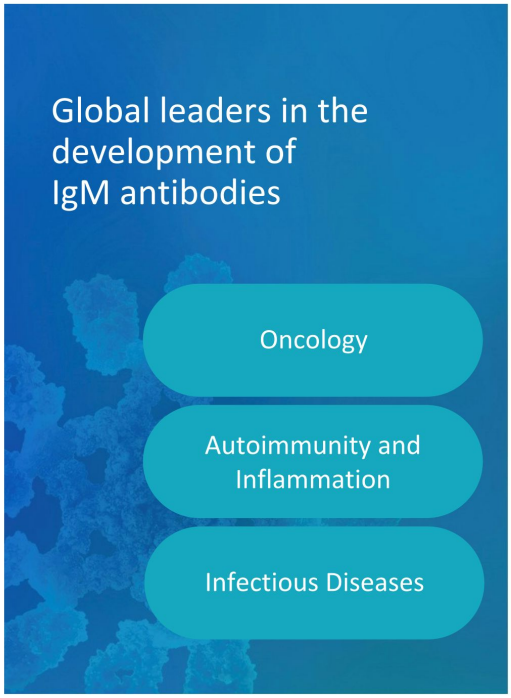
January 6, 2023



Forward-looking statements

This presentation contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These forward-looking statements reflect the current views of the management of IGM Biosciences, Inc. (the "Company," "we" or "our") based on information available to us as of the date hereof. All statements other than statements of historical fact could be deemed forward-looking, including but not limited to statements regarding our unaudited cash and investments balance as of December 31, 2022; our future financial performance; plans, timelines, and expectations related to our preclinical studies, clinical trials, discovery programs and collaboration activities; business plans, strategies, strategic priorities, catalysts and objectives; our ability to obtain regulatory approval; the potential therapeutic benefits and economic value of our product candidates; potential growth opportunities; and our competitive position, industry environment and potential market opportunities. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potentially" "predict," "should," "target," "will" or the negative of these terms or other similar expressions. These forward-looking statements are subject to a number of risks, uncertainties and assumptions, including , among other things: plans, timelines, and expectations related to our preclinical studies, clinical trials and our discovery programs including regarding the availability of data, planned regulatory filings, the initiation and progress of current and future clinical trials; potential delays and disruption resulting from the COVID-19 pandemic, including related supply chain disruptions and constraints; the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of collaborations with third parties, including the agreement with Sanofi; our early stages of clinical drug development; our ability to achieve clinical goals; risks related to the use of engineered IgM antibodies; our ability to utilize our IgM antibody platform to generate and advance additional product candidates; our ability to advance product candidates into, and successfully complete, clinical trials; our ability to adequately demonstrate sufficient safety and efficacy and reduced toxicity, of our product candidates, either alone or in combination with other compounds; the potential for the results of clinical trials to differ from preclinical, preliminary, initial or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; the timing or likelihood of regulatory filings and approvals; our estimates of the number of patients who suffer from the diseases we are targeting and the number of patients that may enroll in our clinical trials; the ability to commercialize our product candidates, if approved; our ability and the potential to successfully manufacture and supply our product candidates for clinical trials and for commercial use, if approved; our ability to accurately forecast future financial results and timelines; our anticipated use of our existing resources, our estimates regarding expenses, future revenue, capital requirements and needs for additional financing and our ability to obtain additional capital; the sufficiency of our existing cash and investments to fund our future operating expenses and capital expenditure requirements; the potential diminishing need for therapeutics to address COVID-19; our ability to attract and retain qualified personnel; the implementation of our business model and strategic plans; the scope of our intellectual property protections we are able to establish and maintain; our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately; developments relating to our competitors and our industry, including competing product candidates and therapies; general economic and market conditions; and other risks described in our public filings with the Securities and Exchange Commission, including our most recent Quarterly Report on Form 10-Q filed on November 3, 2022. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in, or implied by, any forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Additionally, statements that "we believe" and similar statements reflect our management's beliefs and opinions on the relevant subject. These statements are based on information available to us as of the date hereof, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and readers are cautioned not to unduly rely upon these statements. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Except as required by law, we undertake no obligation to update publicly any forward-looking statements for any reason.

This presentation includes information on drug candidates that are under clinical investigation, and which have not yet been approved for marketing by the U.S. Food and Drug Administration. The drug candidates are currently limited by federal law to investigational use, and no representation is made as to their safety or effectiveness for the purposes for which they are being investigated.



IGM Biosciences Overview

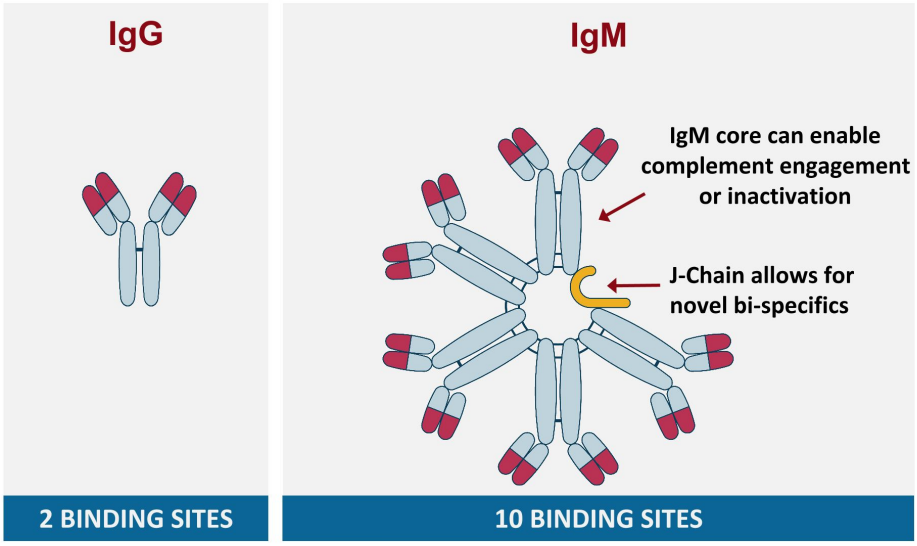
Global leaders in engineering and manufacturing IgM antibodies

- IgM antibodies have structural attributes that provide advantages relative to traditional IgG antibodies in multiple applications
  - Agonist antibodies
  - T cell engaging antibodies
  - Targeted cytokine delivery
- We plan to extend our global leadership position in IgM antibodies in:
  - Clinical development
  - Manufacturing
  - Research
  - Intellectual property
- Cash and investments of $427.2 million (unaudited) as of December 31, 2022

IgM antibodies have unique structural attributes compared to IgG antibodies

Additional binding sites lead to:

- Superior total binding power (avidity)
- Increased cross-linking of receptors for greater agonism



Strategic priorities for 2023

Accelerate development of our agonist Death Receptor 5 IgM antibody (IGM-8444)

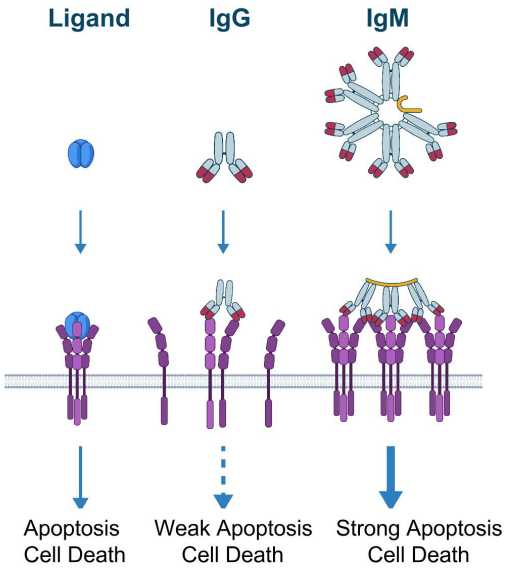
Develop our IgM T cell engager antibodies in autoimmune disease

Extend our clinical pipeline

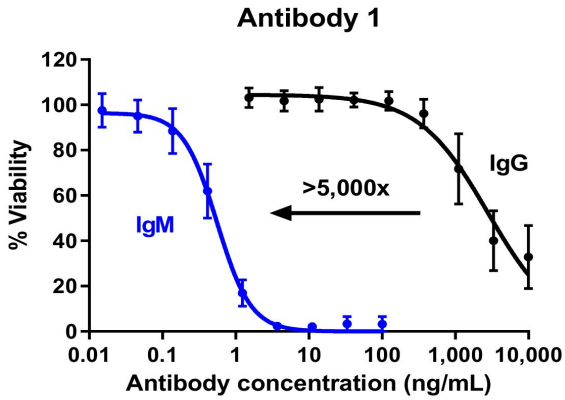
Continue to develop our IgM antibody platform

Strong DR5 activation requires multi-receptor agonism

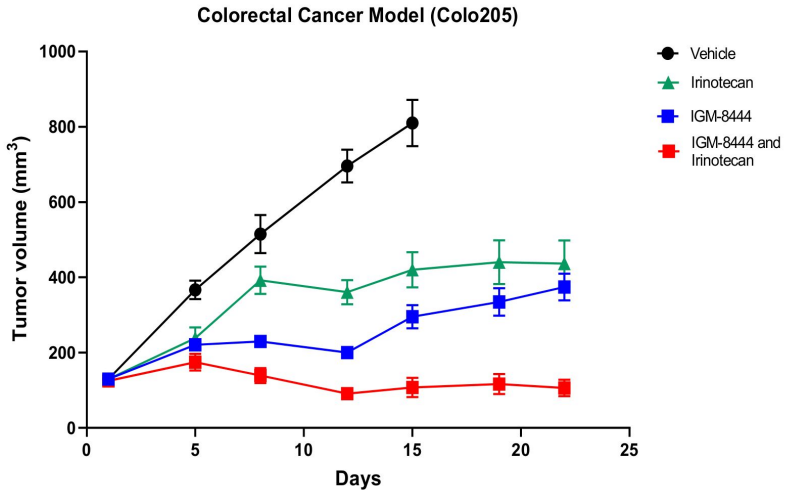
DR5 is highly expressed across many different tumor types



In vitro apoptosis comparing IgG and IgM DR5 antibodies using the same binding domain

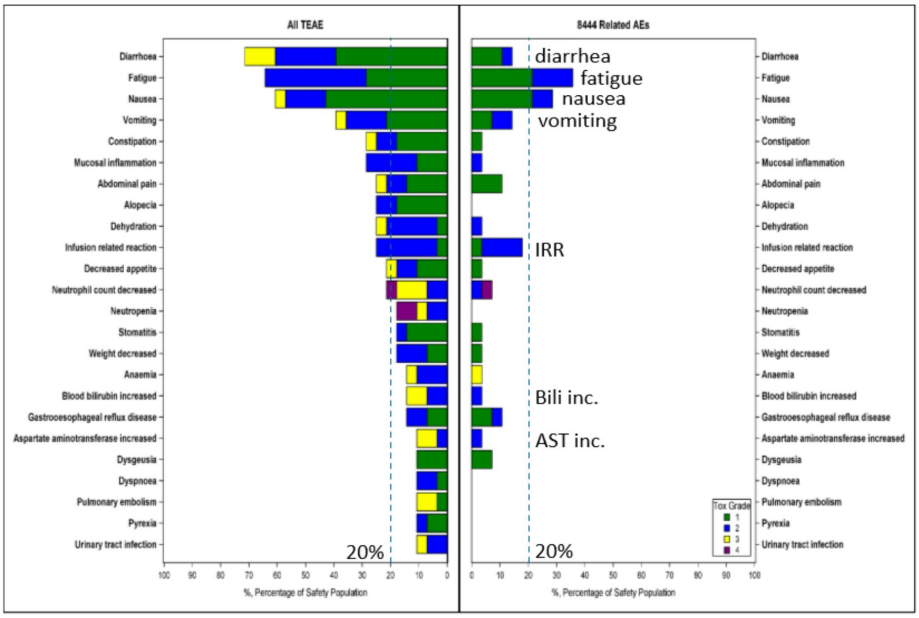


IGM-8444: activity seen in combination with irinotecan (*in vivo*)
One of the active agents in FOLFIRI chemotherapy treatment



IGM-8444 (5 mg/kg Q2D x 7)
Irinotecan (100 mg/kg QW x 3)

IGM-8444: encouraging clinical safety profile in FOLFIRI combination
Treatment-emergent adverse events in FOLFIRI combination cohorts



28 total patients treated with IGM-8444 + FOLFIRI

DLTs: None

SAEs: 8 patients - all **unrelated**

Grade 3+ AEs: Two **related** Grade 3 events (anemia and neutropenia) considered related to **both** FOLFIRI and IGM-8444.

IRRs: Low grade (Gr1/Gr2) and manageable with pre-medications and longer infusion

Hepatotoxicity: **No related Grade 3+ events**. All low grade (Gr1/Gr2) LFT or bilirubin elevations with no clinical sequelae

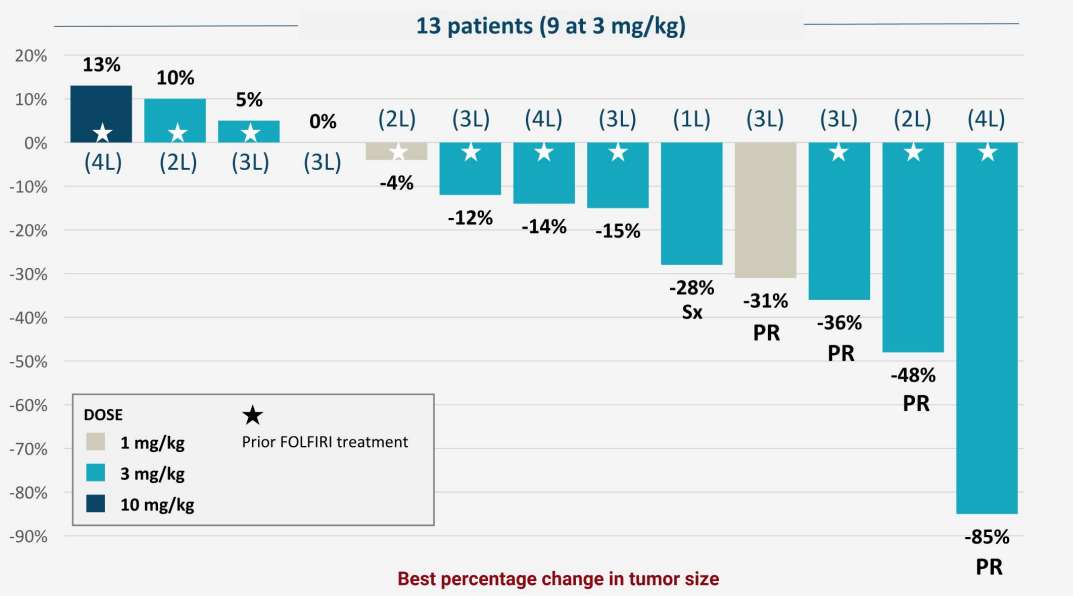
Data cut-off: December 16, 2022

igm biosciences

IGM-8444: Encouraging efficacy profile in colorectal cancer (CRC) combination. Strong rationale for randomized CRC study with FOLFIRI

All CRC patients treated in second through fourth FOLFIRI combo cohorts who are time eligible for second scan by data cut-off

- **All prior FOLFIRI patients showing tumor shrinkage progressed or had stable disease as best response to prior FOLFIRI treatment**
- **3L+ Median PFS: 5.5 months (9 patients)**
  - Longest 3L+ progression free survival 12+ months
  - 3L CRC SOC: PFS ~2 months, OS ~7 months



SOC-standard of care; PFS-progression-free survival; OS-overall survival; Sx – Surgery; PR – Partial Response
Data cut-off: December 31, 2022

9

Selected patient profiles: substantial benefit observed in patient's refractory to prior FOLFOX/FOLFIRI treatment

69, mCRC, MSS, KRASmt, BRAFwt
Prior FOLFIRI progression

Prior Treatments	Time on Tx	Outcome
Xeloda	5m	
FOLFIRI + bev	**5m**	**SD → PD**
XELOX	**2m**	**SD → PD**
IGM-8444 + FOLFIRI	**12m+**	**PR (-36%)***

*Response Confirmed

47, mCRCMSI-low, BRAFwt, KRASmt (G12D)
Prior FOLFIRI progression

Prior Treatments	Time on Tx	Outcome
FOLFOX6 → Xeloda/XRT	2 + 1m	
FOLFIRI + bev	**5m**	**NED → PD**
FOLFIRI + bev	**3m**	**SD → PD**
Clinical Trial	**2m**	**PD**
IGM-8444 + FOLFIRI	**8.3**	**PR (-85%)***

*Response Confirmed

52, mCRC, MSI-low, KRASwt, BRAFwt

Prior Treatments	Time on Tx	Outcome
FOLFOX	6m	**NED → PD**
IGM-8444 + FOLFIRI	**5m**	**(-28%) → Treatment qualified patient for curative surgery**

*Response Confirmed

63, mCRC, NRASmt, KRASwt, BRAFwt,
Prior FOLFIRI experience

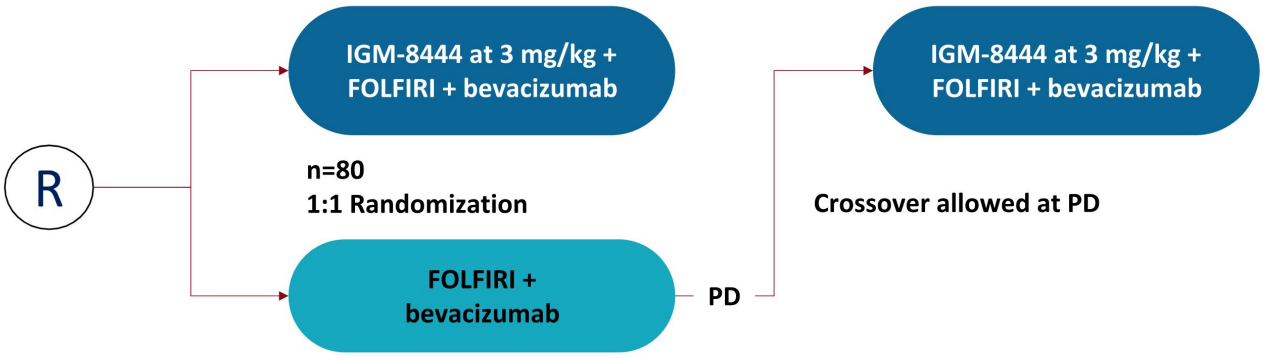
Prior Treatments	Time on Tx	Outcome
FOLFOX6	6m	SD → PD
FOLFIRI + bev	**2m**	**SD → SD**
IGM-8444 + FOLFIRI	**5.8m**	**PR (-48%)***

Data cut-off: December 31, 2022

bev-bevacizumab; m-mths; SD-stable disease; PD-progressive disease; NED-no evidence of disease

igm biosciences

Randomized second line metastatic colorectal cancer trial
Expected initiation: Q1 2023



Population

- Global Trial
- 2L CRC
- Prior FOLFIRI excluded
- Tumor mutation status agnostic

Stratification Factors

- Liver metastases
- KRAS status

Statistical Analysis Plan

- Primary endpoint: overall response rate
- Secondary endpoints: PFS, OS, safety

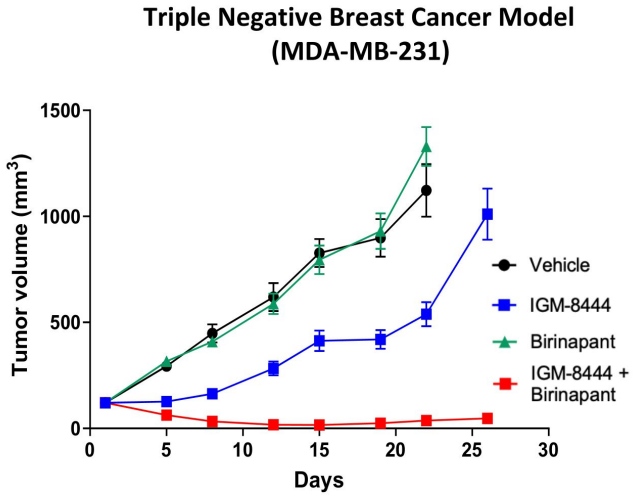
Initial focus of IGM-8444 development: improving FOLFIRI + bevacizumab, the most common regimen for 2L colorectal cancer

	1L	2L	3L+
Current Standard of Care	**FOLFOX** (or other 5-FU chemo combos) + targeted agents	**FOLFIRI** (or other 5-FU chemo combos) ± targeted agents	Various
	• Bevacizumab • EGFR mAb (RASwt only) • Pembrolizumab (MSI-H only)	• Bevacizumab • EGFR mAb (RASwt only)	• Regorafenib • Trifluridine/tipiracil • Other Chemotherapy
Efficacy Benchmark	ORR: ~55% mPFS: ~10+m mOS: 24+ mos	**ORR: 5-20%** **mPFS: ~ 6 m** **mOS: ~ 12 m**	ORR: 1-2% mPFS: ~ 2 m mOS: ~ 6 m
US Patient Incidence*	~50,000/year	~30,000/year	~20,000/year

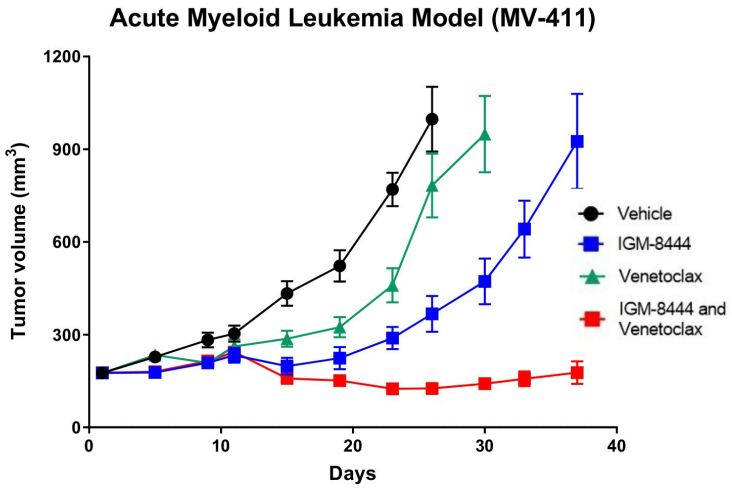
Limited effectiveness of later line therapies: low ORR and survival durations

* Source: GlobalData accessed October 2022

Synergistic activity seen in combination with other apoptotic pathway drugs: venetoclax and birinapant (*in vivo*)



DR5: extrinsic apoptotic pathway
Birinapant: intrinsic apoptotic pathway



DR5: extrinsic apoptotic pathway
Venetoclax: intrinsic apoptotic pathway

Source: Sinclair, A. "Multimeric IgM antibodies targeting DR5 are potent and rapid inducers of tumor cell apoptosis In Vitro and In Vivo" PEGS Europe, November 2021. Data on file.

Additional IGM-8444 ongoing combination studies

Additional Combination Cohorts	IGM-8444 + Birinapant	IGM-8444 + Venetoclax
Planned Activities	• 4th dose cohort currently being tested • No DLTs observed • Solid tumors, all comers	• 1st cohort open in SLL/CLL • 1st cohort open in AML (venetoclax plus azacytidine)

Data cut-off: December 16, 2022

Strategic priorities for 2023

Accelerate development of our agonist Death Receptor 5 IgM antibody (IGM-8444)

Develop our IgM T cell engager antibodies in autoimmune disease

Extend our clinical pipeline

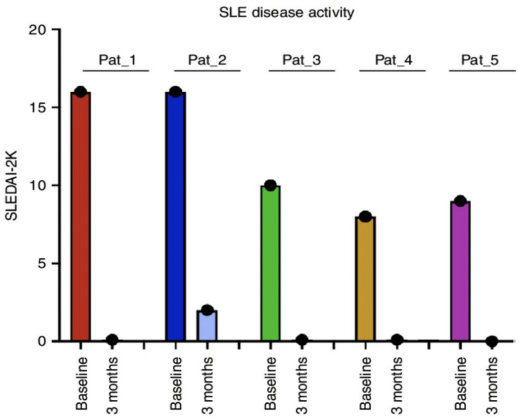
Continue to develop our IgM antibody platform

Using T cells to treat autoimmune disease via deep B cell depletion

Recent proof of concept data showed extensive B cell depletion using an anti-CD19 CAR-T can treat autoimmune patients and potentially reset their immune systems

- 5 patients with treatment refractory systemic lupus erythematosus (SLE) treated with anti-CD19 CAR-T
- Resulted in durable, drug-free remission and shift to more naïve immunophenotype

Depletion of pathogenic immune cells deep within the tissues appears to be critical to this result

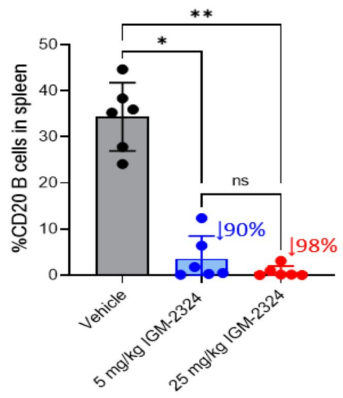


Mackensen et al., Anti-CD19 CAR T cell therapy for refractory systemic lupus erythematosus, Nature Medicine, October 2022.

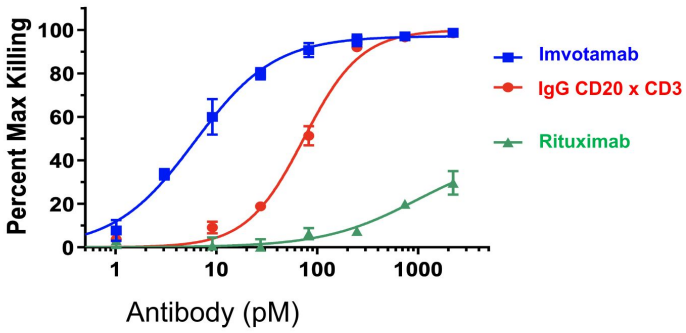
T cell engagement with imvotamab can enable deep B cell depletion

Deep B cell depletion in tissues and depletion of low CD20 B cells

Deep depletion of CD20+ cells within tissue (*in vivo*)
Spleen



More effective depletion of low CD20 expressing cells than rituximab or IgG CD20 x CD3 (*in vitro*)



Imvotamab non-human primate cross reactive surrogate achieves >85% reduction of CD20+ B cells in spleen, mesenteric lymph nodes and bone marrow

Opportunity for IgM T cell engager antibodies in autoimmune disease

- CD20 targeted antibodies are used with varying degrees of success in a broad range of autoimmune diseases, including systemic lupus erythematosus (SLE), rheumatoid arthritis and multiple sclerosis
- Monospecific anti-CD20 antibodies deplete circulating B cells, but are less effective in depleting immune cells in tissues where NK cells and complement are less available
  - Reservoirs of pathogenic auto-antibody producing cells can persist and drive further disease
- Imvotamab has shown an advantageous safety profile among CD20 x CD3 T cell engagers

We plan to file INDs in 2023 for imvotamab in multiple autoimmune diseases

First IND is planned to be in SLE

IGM-2644 (CD38 x CD3) may also provide an alternative or additional approach to immune cell depletion

Strategic priorities for 2023

Accelerate development of our agonist Death Receptor 5 IgM antibody (IGM-8444)

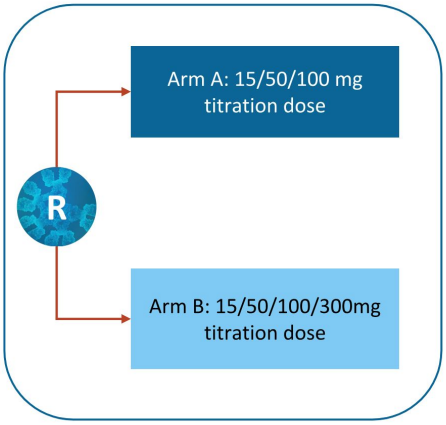
Develop our IgM T cell engager antibodies in autoimmune disease

Extend our clinical pipeline

Continue to develop our IgM antibody platform

Imvotamab oncology clinical development

Monotherapy dose finding studies



- Dose selection: 100mg vs. 300mg
- DLBCL and Follicular Lymphoma
- Up to 30 patients per arm, per disease
- Dose finding in DLBCL expected Q2 2023

Potential combination studies

imvotamab + loncastuximab R/R NHL*

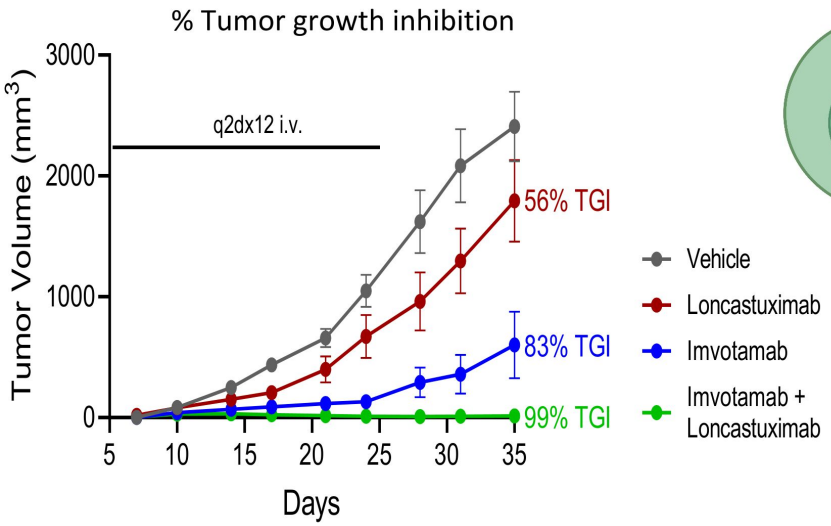
imvotamab + tafasitamab + lenalidomide

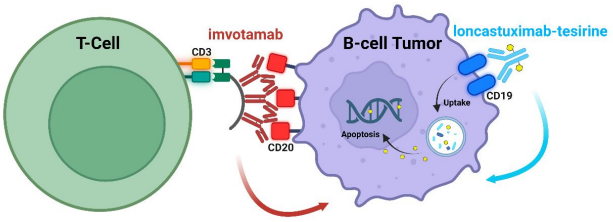
Imvotamab + immunomodulatory drugs

- Imvotamab + loncastuximab study expected to begin in Q1 2023
- Additional combination studies under consideration

* Combination will start with a full dose of loncastuximab with 100 mg of imvotamab

Imvotamab plus loncastuximab: increased potency (*in vivo*)
Two tumor targets, two mechanisms of action: reduced chance for escape

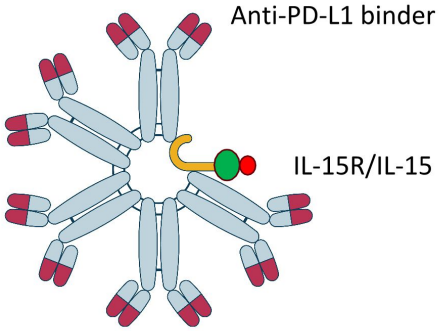




- Efficacy model is Raji s.c. with human PBMC engraftment
- 5 mg/kg imvotamab q2dx12 i.v. starting on day 5
- 0.1 mg/kg loncastuximab is a single i.p. dose on day 5 (prior to imvotamab)

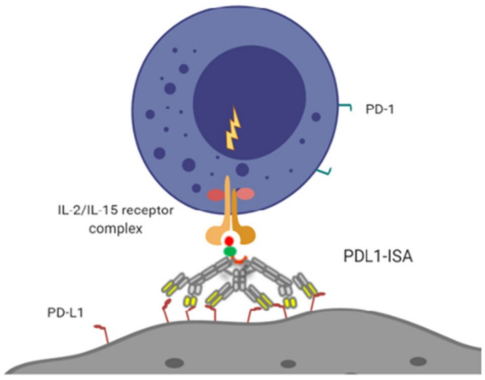
IGM-7354: Targeted IL-15 delivery via PD-L1 expressing cells

IGM - 7354



IL-15/IL-15R x anti-PDL1 IgM

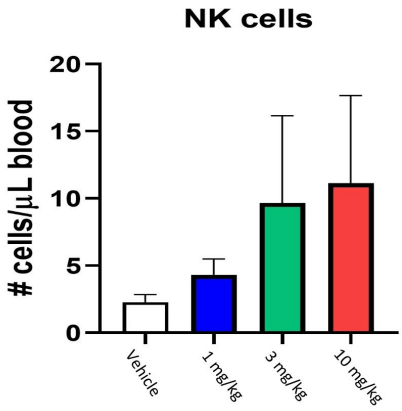
NK or CD8 T cell expansion



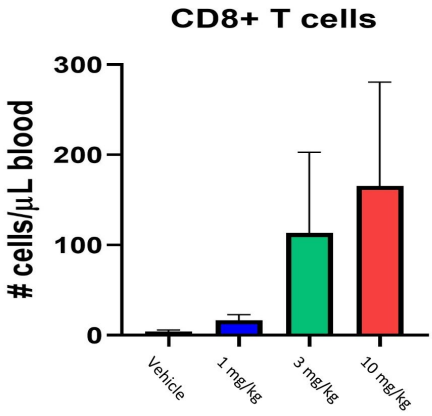
Tumor and/or Antigen Presenting Cell

- IGM-7354 presents IL-15 to CD8 and NK cells
- Targeted delivery may increase efficacy and reduce toxicity
- First patient dosing expected: Q1, 2023

Immune stimulation with IGM-7354



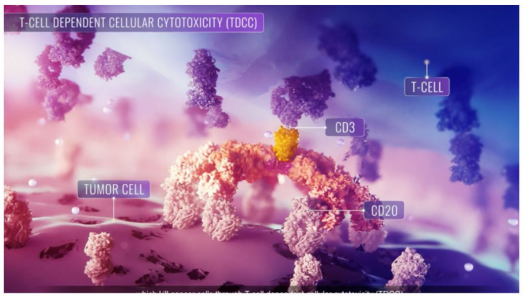
(*in vivo*)



(*in vivo*)

Adapted from Giffon et al., AACR 2022

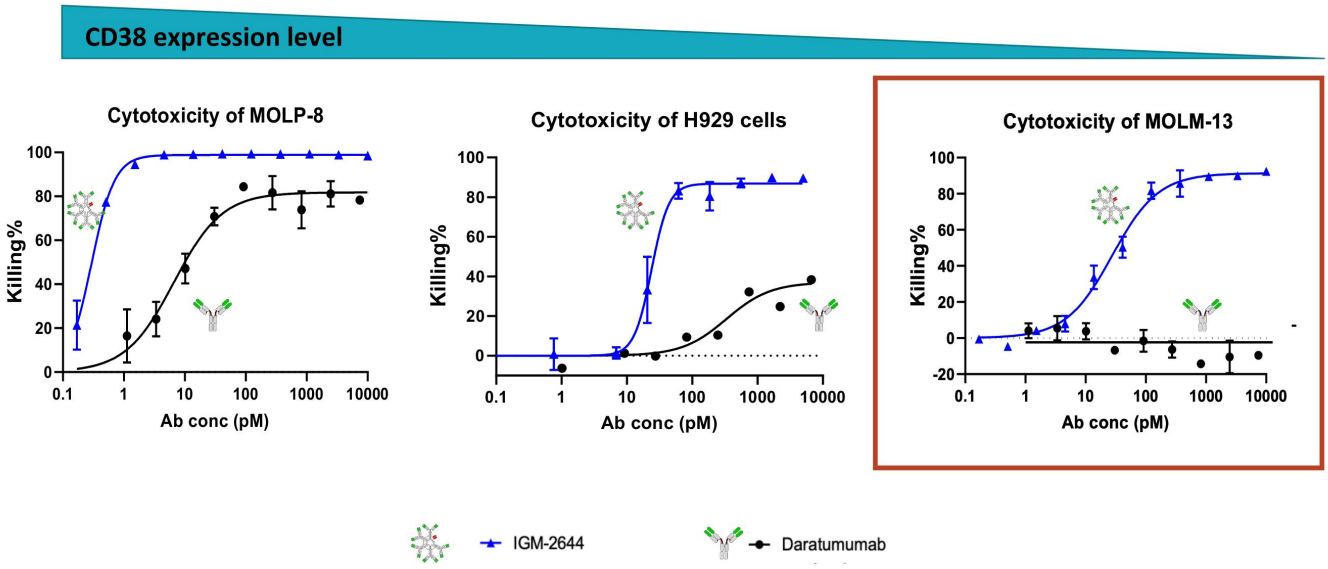
Expansion of T Cell engager platform beyond imvotamab



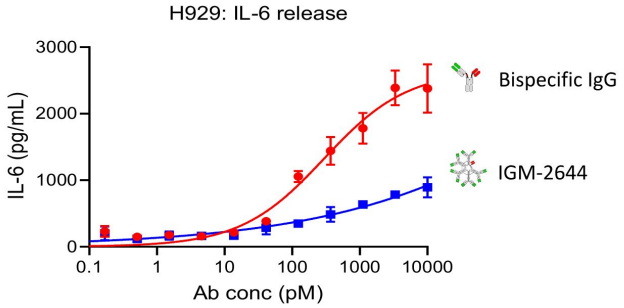
	Indications	Timing
IGM-2644 CD38 x CD3	Multiple Myeloma Autoimmunity	Multiple Myeloma Phase 1 study initiation expected Q1 2023
IGM-2537 CD123 x CD3	• AML • MDS • ALL	AML Phase 1 study initiation expected H2 2023

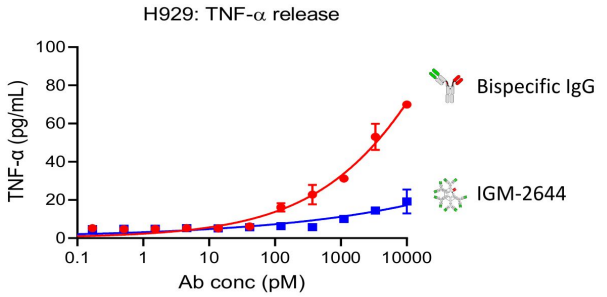
IGM-2644 (CD38 x CD3) shows robust activity in pre-clinical models

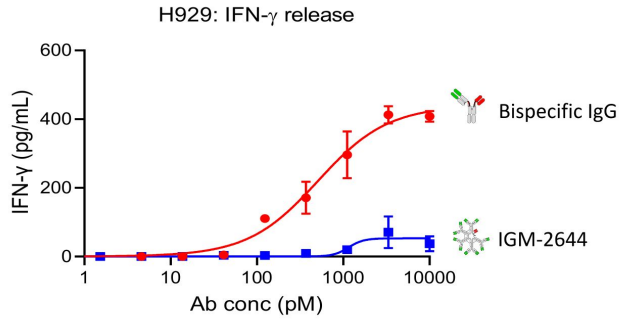
Differentiated potency against low CD38 expression cells (*in vitro*)

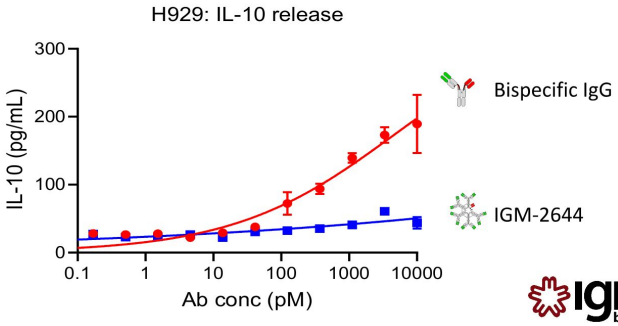


IGM-2644: reduced cytokine release relative to bispecific IgG (*in vitro*)

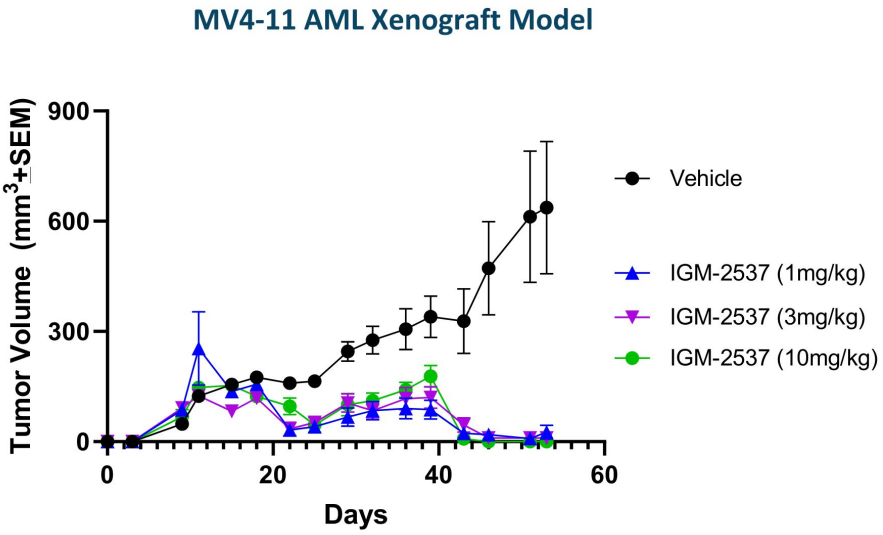




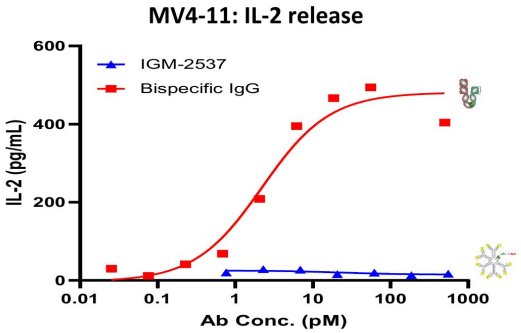


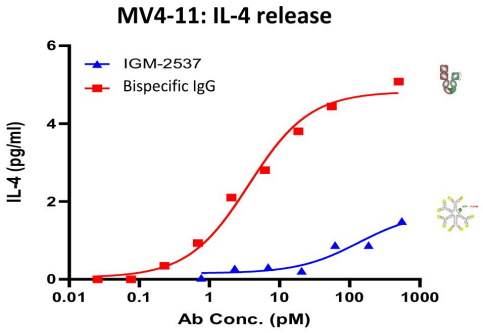


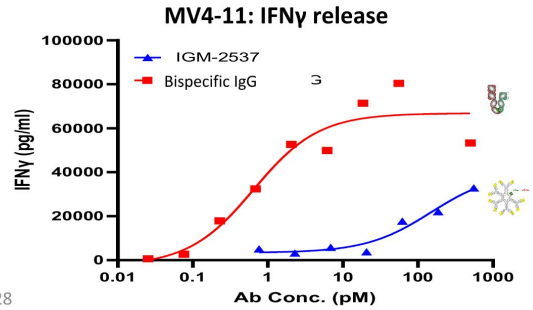
IGM-2537 (CD123 x CD3): Robust activity in acute myeloid leukemia model (*in vivo*)



IGM-2537: Reduced cytokine release relative to bispecific IgG (*in vitro*)







Reduced cytokine release compared to bispecific IgG

Strategic priorities for 2023

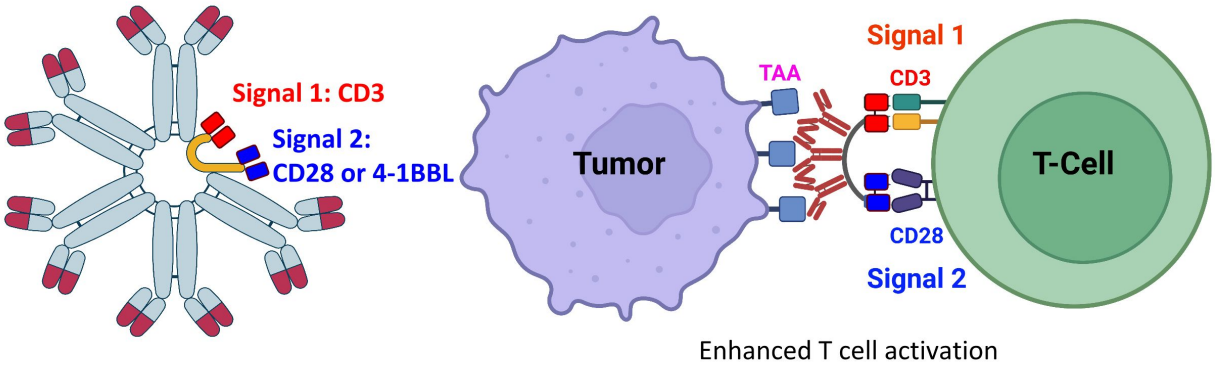
Accelerate development of our agonist Death Receptor 5 IgM antibody (IGM-8444)

Develop our IgM T cell engager antibodies in autoimmune disease

Extend our clinical pipeline

Continue to develop our IgM antibody platform

Next Generation: Co-stimulatory IgM T cell engagers
Two activation signals within single immune synapse

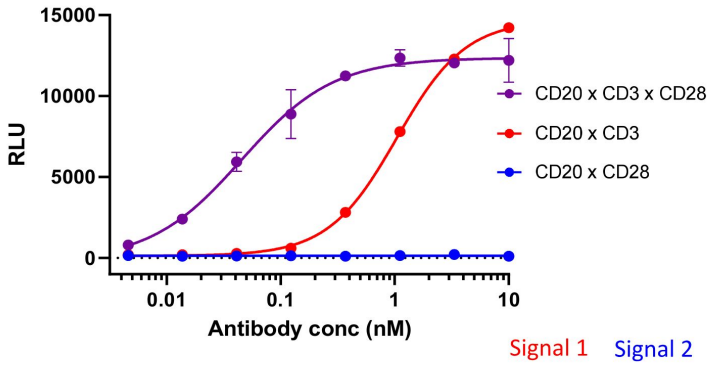


Enhanced T cell activation

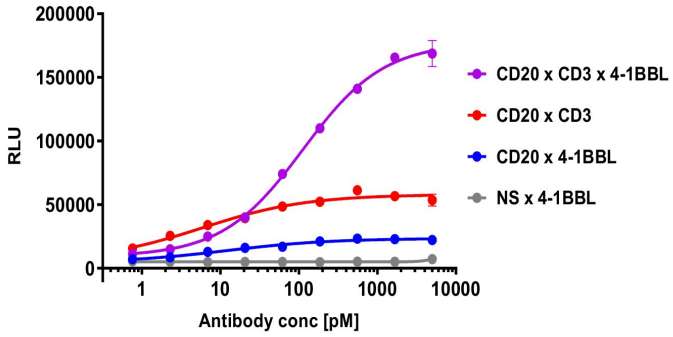
- CD28 or 41BBL co-stimulation provides increased T cell activation and proliferation for sustained anti-tumor response
- IgM platform allows dual-engagement while maintaining full avidity advantage for tumor targeting
- Potential for responses in “cold” solid tumor setting with low T cell counts

T cell co-stimulation can create significantly enhanced T cell activation (*in vitro*)

CD28 co-stimulation with CD3
(T-cell activation)



4-1BBL co-stimulation with CD3
(T-cell Activation)*



Signal 1 Signal 2 Signal 1+2

*T cell activation uses a 4-1BB expressing reporter cell activation assay

Novel therapeutic approaches to address infectious diseases

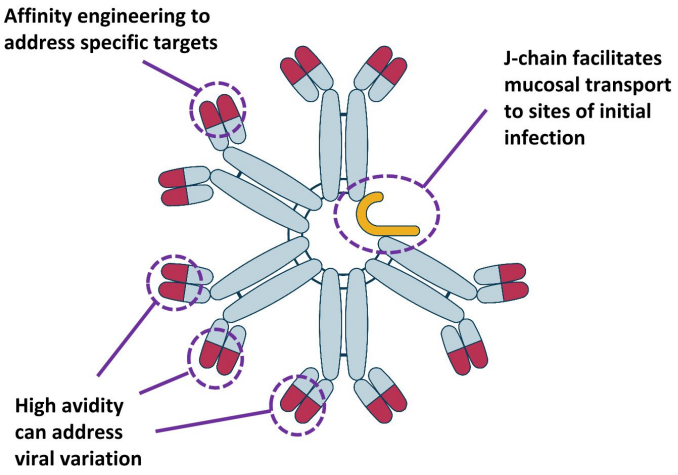
IgMs evolutionarily designed as "the first line of humoral defense"

- First antibody defense upon pathogen infection
- Avidity provides broad protection against pathogens
- Stronger complement fixation than IgG antibodies

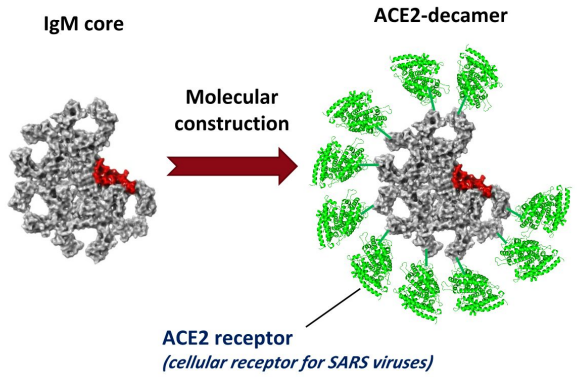
Differentiated applications in infectious diseases

- "Virus trapping" antivirals
- Aerosolized/inhaled therapeutics

Opportunities to maximize therapeutic potential

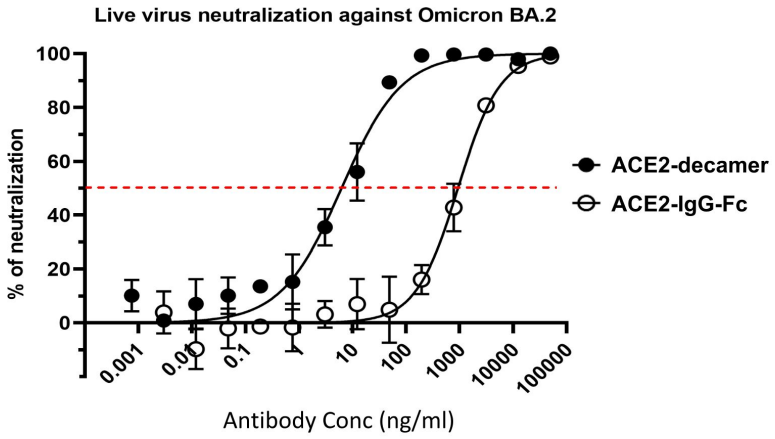


Viral trapping strategy: IgM structure/avidity enables virus neutralization by “trapping” the virus using its cellular receptor



Valency of IgM enables potent virus neutralization

ACE2-decamer is ~100x more potent than bivalent ACE2-IgG-Fc in neutralizing Omicron and other variants (*in vitro*)

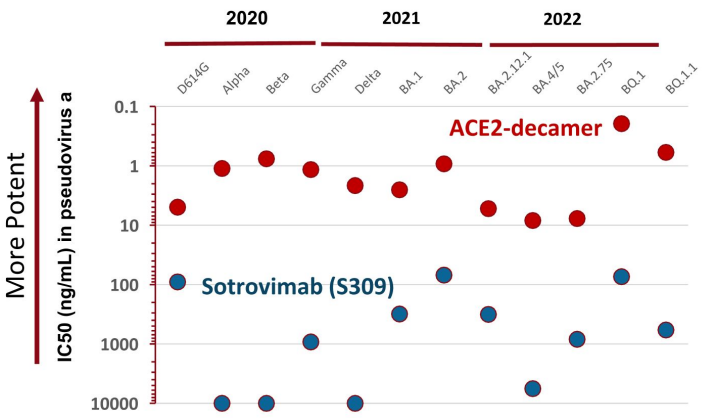


IgM virus trapping is a novel antiviral strategy designed to be resilient against viral evolution

- Antiviral potency of ACE2-decamer designed to be retained despite viral mutations
  - SARS-family viruses may not be able to change dependence on their sole receptor (ACE2) for infection
  - Designed to improve potency as virus evolves to increase ACE2 receptor binding affinity
  - SARS-CoV-1 (Urbani strain) neutralized with similarly high potency

ACE2-decamer is designed to neutralize all viruses that rely solely on the ACE2 receptor for entry

Consistently high potency across SARS-COV2 variants



*Sotrovimab initially approved under EUA in 2020 but removed due to reduced potency against variants

igm biosciences

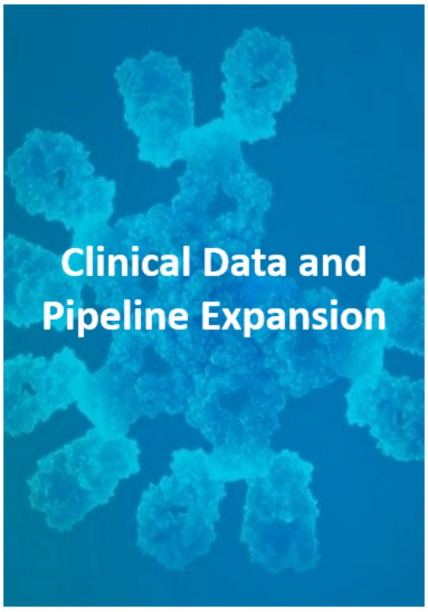
Sanofi/IGM multi-target collaboration agreement

Global research collaboration to leverage proprietary IgM antibody technology platform to create, develop and commercialize agonists against **three oncology targets** and **three autoimmunity and inflammation targets**

Financial Terms

- $150M upfront payment received
- Equity investment in April 2022 follow-on offering
- Potentially $6B+ in preclinical, clinical, regulatory and commercial milestone payments
- Sanofi responsible for worldwide commercialization

Multiple catalysts anticipated over next eighteen months



IGM-8444 (DR5)

- ❑ Initial randomized IGM-8444 + FOLFIRI + bevacizumab data in 2L colorectal cancer patients

Imvotamab (CD20 x CD3)

- ❑ Initial clinical data in autoimmune patients
- ❑ Initial loncastuximab combination data

IGM-2644 (CD38 x CD3)

- ❑ Initial multiple myeloma data
- ❑ Initiate clinical testing in autoimmune patients

IGM-7354 (IL15 x PD-L1)

- ❑ Initial clinical data in solid tumor patients

IGM-2537 (CD123 x CD3)

- ❑ Initiate clinical testing in AML patients

Global Leaders in IgM Antibodies