IGM Biosciences Announces Second Quarter 2021 Financial Results and Provides Corporate Update

August 9, 2021

– Recommended Phase 2 Dose of IGM-2323 Expected in 2021 –

– Initial Data from Phase 1 Trial of IGM-8444 in Solid Cancers Expected in 2021 –

– Expansion of IgM Platform into Infectious Diseases –

MOUNTAIN VIEW, Calif., Aug. 09, 2021 (GLOBE NEWSWIRE) -- IGM Biosciences, Inc. (Nasdaq: IGMS), a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies, today announced its financial results for the second quarter ended June 30, 2021 and provided an update on recent developments.

"We continue to make steady progress in the development of our innovative product pipeline, including the successful completion of the initial dose escalation portion of our IGM-2323 Phase 1 clinical trial," said Fred Schwarzer, Chief Executive Officer of IGM Biosciences. "We look forward to announcing a recommended Phase 2 dose for IGM-2323, presenting initial dose escalation data from the Phase 1 trial of IGM-8444, initiating a Phase 1 trial for IGM-6268 and filing an IND for IGM-7354 this year."

Pipeline Updates

IGM-2323

- **Phase 1 dose escalation completed; dose expansion continues.** IGM continues to advance the clinical development of IGM-2323, the Company's IgM-based CD20 x CD3 bispecific antibody, for the treatment of non-Hodgkin's lymphoma (NHL). The Company cleared its highest planned dose escalation cohort, a top dose of 1000 mg, without a dose limiting toxicity, and is currently treating additional patients in four Phase 1 dose cohorts with top doses of 100 mg, 300 mg, 600 mg and 1000 mg, respectively. IGM expects to select a recommended Phase 2 dose in 2021.

IGM-8444

- **Additional dose cohorts cleared in Phase 1.** IGM continues to advance the clinical development of IGM-8444, the Company's IgM Death Receptor 5 (DR5) agonist, for the treatment of a potentially broad range of solid tumors and hematologic malignancies. IGM has cleared its third dose cohort (3 mg/kg) of the single-agent portion of its Phase 1 clinical study and is currently treating patients in its highest dose escalation cohort (10 mg/kg) with every two-week single agent dosing. IGM has also cleared the first dose cohort of the FOLFIRI combination portion of the Phase 1 study and is currently treating patients in the second of four planned FOLFIRI combination dose escalation cohorts. IGM expects to report initial data from the dose escalation portion of the Phase 1 trial in 2021.

- **Clinical testing of birinapant in combination with IGM-8444 expected to begin this year.** IGM remains on track to begin clinical testing of birinapant in combination with IGM-8444 in 2021.

IGM-6268

- **New pipeline candidate for the treatment and prevention of COVID-19 expected to advance into the clinic this year.** In June 2021, IGM announced IGM-6268, which represents the expansion of the Company's IgM platform into infectious diseases. IGM-6268 is an IgM version of an anti-SARS-CoV-2 IgG monoclonal antibody and is being developed as an intranasally administered agent for the treatment and prevention of COVID-19. IGM expects to initiate a Phase 1 clinical trial of IGM-6268 in 2021.

- ***Nature* manuscript published.** In June 2021, *Nature* published an article entitled "Nasal delivery of an IgM offers broad protection from SARS-CoV-2 variants". The article describes results from preclinical studies demonstrating significantly greater neutralization of SARS-CoV-2 with an IgM antibody compared to IgG antibodies, the potent neutralization of all evaluated mutant Variants of Concern and Variants of Interest, and the ability to provide effective preventative and therapeutic protection when delivered intranasally in mice. The article was co-authored by researchers at IGM, The University of Texas Medical Branch at Galveston and The University of Texas Health Science Center at Houston.

IGM-7354

- **Investigational New Drug (IND) application expected to be filed this year.** IGM plans to file an IND application with the U.S. Food and Drug Administration (FDA) for IGM-7354, the Company's IL-15 x PD-L1 bispecific IgM antibody, before the end of 2021 in order to begin clinical testing initially in solid tumors, followed by hematologic malignancies.

Corporate Updates

- **Chris Takimoto appointed Chief Medical Officer**. Dr. Takimoto brings 30 years of experience in cancer research and development. Most recently, Dr. Takimoto was Senior Vice President, Oncology at Gilead Sciences, Inc. Prior to Gilead, he served as Chief Medical Officer of Forty Seven, Inc., a biotechnology company formed out of Stanford University and acquired by Gilead Sciences in 2020.

Second Quarter 2021 Financial Results

- **Cash and Investments:** Cash and investments as of June 30, 2021 were $301.8 million, compared to $366.3 million as of December 31, 2020.
- **Research and Development (R&D) Expenses:** For the second quarter of 2021, R&D expenses were $30.1 million, compared to $15.0 million for the same period in 2020.
- **General and Administrative (G&A) Expenses:** For the second quarter of 2021, G&A expenses were $8.6 million, compared to $4.4 million for the same period in 2020.
- **Net Loss:** For the second quarter of 2021, net loss was $38.7 million, or a loss of $1.16 per share, compared to a net loss of $18.8 million, or a loss of $0.62 per share, for the same period in 2020.

2021 Financial Guidance

IGM reiterates its previously issued financial guidance expecting full year GAAP operating expenses to be between $175 million and $185 million including estimated non-cash stock-based compensation expense of approximately $25 million. IGM expects to end 2021 with a balance of over $200 million in cash and investments.

About IGM Biosciences, Inc.

Headquartered in Mountain View, California, IGM Biosciences is a clinical-stage biotechnology company focused on creating and developing engineered IgM antibodies. Since 2010, IGM Biosciences has worked to overcome the manufacturing and protein engineering hurdles that have limited the therapeutic use of IgM antibodies. Through its efforts, IGM Biosciences has created a proprietary IgM technology platform for the development of IgM antibodies for those clinical indications where their inherent properties may provide advantages as compared to IgG antibodies.

Cautionary Note Regarding Forward-Looking Statements

This press release contains forward-looking statements, including statements relating to IGM's plans, expectations and forecasts and to future events. Such forward-looking statements include, but are not limited to: the potential of, and expectations regarding IGM's technology platform, its antibody drug candidates and birinapant; statements regarding IGM's Phase 1 clinical trials of IGM-2323 and IGM-8444; the anticipated timing of the selection of a recommended Phase 2 dose for IGM-2323, the reporting of initial data from the dose escalation portion of the Phase 1 trial of IGM-8444, the initiation of clinical testing of birinapant in combination with IGM-8444, the initiation of a Phase 1 trial for IGM-6268 and an IND filing for IGM-7354; IGM's expectations regarding its financial position, including operating expenses, cash and investments and non-cash stock-based compensation; and statements by the Chief Executive Officer of IGM. Such statements are subject to numerous important factors, risks and uncertainties that may cause actual events or results to differ materially, including but not limited to: potential delays and disruption resulting from the COVID-19 pandemic and governmental responses to the pandemic, including any future impacts to IGM's operations, the manufacturing of its product candidates, the progression of its clinical trials, enrollment in its current and future clinical trials and progression of its collaborations and related efforts; IGM's early stages of clinical drug development; risks related to the use of engineered IgM antibodies, which is a novel and unproven therapeutic approach; IGM's ability to demonstrate the safety and efficacy of its product candidates; IGM's ability to successfully and timely advance its product candidates through preclinical studies and clinical trials; IGM's ability to enroll patients in its clinical trials; the potential for the results of clinical trials to differ from preclinical, preliminary or expected results; the risk of significant adverse events, toxicities or other undesirable side effects; IGM's ability to successfully manufacture and supply its product candidates for clinical trials; the risk that all necessary regulatory approvals cannot be obtained; the risk that the potential benefits of combination therapies do not outweigh their costs; IGM's ability to obtain additional capital to finance its operations, if needed; uncertainties related to the projections of the size of patient populations suffering from the diseases IGM is targeting; IGM's ability to obtain, maintain and protect its intellectual property rights; developments relating to IGM's competitors and its industry, including competing product candidates and therapies; risks related to collaborations with third parties, including the risk of the occurrence of any event, change or other circumstance that could give rise to the termination of any such collaboration; general economic and market conditions; and other risks and uncertainties, including those more fully described in IGM's filings with the Securities and Exchange Commission (SEC), including IGM's Annual Report on Form 10-K filed with the SEC on March 30, 2021, IGM's Quarterly Report on Form 10-Q filed with the SEC on August 9, 2021 and in IGM's future reports to be filed with the SEC. Any forward-looking statements contained in this press release speak only as of the date hereof, and IGM specifically disclaims any obligation to update any forward-looking statement, except as required by law.

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IGM Biosciences, Inc.
Selected Statement of Operations Data
(unaudited)
(in thousands, except share and per share data)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development [1]	$ 30,089	$ 15,019	$ 53,661	$ 29,602
General and administrative [1]	8,649	4,388	16,783	8,378
Total operating expenses	38,738	19,407	70,444	37,980
Loss from operations	(38,738)	(19,407)	(70,444)	(37,980)
Other income, net	24	568	86	1,517
Net loss	$ (38,714)	$ (18,839)	$ (70,358)	$ (36,463)
Net loss per share, basic and diluted	$ (1.16)	$ (0.62)	$ (2.11)	$ (1.19)
Weighted-average common shares outstanding, basic and diluted	33,371,753	30,551,736	33,350,492	30,521,600

[1] Amounts include stock-based compensation expense as follows:

Research and development	$ 2,645	$ 1,047	$ 4,510	$ 1,713
General and administrative	2,964	908	6,603	1,565
Total stock-based compensation expense	$ 5,609	$ 1,955	$ 11,113	$ 3,278

IGM Biosciences, Inc.
Selected Balance Sheet Data
(unaudited)
(in thousands)

	June 30, 2021	December 31, 2020
Cash and investments	$ 301,834	$ 366,269
Total assets	350,664	408,632
Accounts payable	4,853	7,924
Accrued liabilities	10,713	6,649
Total liabilities	28,208	26,817
Accumulated deficit	(258,918)	(188,560)
Total stockholders' equity	322,456	381,815

Source: IGM Biosciences, Inc.