IDEAYA Biosciences, Inc. Reports First Quarter 2020 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., May 12, 2020 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics, provided a business update and announced financial results for the first quarter ended March 31, 2020.

"IDEAYA continues to advance development of IDE196 in our Phase 1/2 tissue-agnostic basket trial in patients with solid tumors harboring GNAQ or GNA11 (GNAQ/11). We are generally not experiencing substantial impact from the COVID-19 pandemic on our IDE196 clinical program. We have completed enrollment of patients in the metastatic uveal melanoma (MUM) Phase 1 portion of the clinical trial and are continuing enrollment of GNAQ/11 patients with other solid tumors, such as cutaneous melanoma and colorectal cancer, in an ongoing Phase 2 portion of the clinical trial. We also remain on track for initiating a new cohort in this clinical trial to evaluate IDE196 in combination with binimetinib under a clinical trial collaboration and supply agreement with Pfizer," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

IDEAYA is also advancing its MAT2A program for patients having tumors with MTAP deletion. The company has selected a lead compound MAT2A inhibitor, and remains on track to file an IND for a differentiated and potential best-in-class MAT2A inhibitor development candidate in the fourth quarter of 2020.

IDEAYA's broad pipeline of synthetic lethality programs also includes Pol theta for tumors with BRCA or other homologous recombination deficiency (HRD) mutations, Werner helicase (WRN) for tumors with high microsatellite instability (MSI), and PARG for tumors with BRCA2 mutations, impaired base excision repair, or replication stress signature. The company is also advancing early discovery efforts on multiple undisclosed synthetic lethality targets.

Key highlights for IDEAYA's research and development programs include:

Clinical IDE196 Program

IDE196

Continued to execute on IDEAYA's Phase 1/2 tissue-type agnostic basket trial, initiated in June 2019, to evaluate IDE196 in solid tumors harboring activating GNAQ/11 mutations, entitled "*A phase 1/2 study of IDE196 in patients with solid tumors harboring GNAQ/11 mutations or PRKC fusions"* (ClinicalTrials.gov Identifier: NCT03947385). As of May 1, 2020, unless otherwise noted:

- Enrolled 56 patients in IDE196 monotherapy arm of Phase 1/2 clinical trial
    - Completed enrollment and ongoing evaluation of IDE196 in the MUM monotherapy arm, with aggregate enrollment of 51 patients in the Phase 1 dose escalation and tablet formulation studies
    - Ongoing enrollment into the Phase 2 expansion arm for IDE196 as a monotherapy in solid tumors other than MUM having GNAQ or GNA11 hotspot mutations, with aggregate Phase 1/2 enrollment of 5 cutaneous melanoma patients

- Completed evaluation of the tablet formulation of IDE196 in MUM patients in a Phase 1 sub-study, with the pharmacokinetic profile of the tablet formulation comparable to the powder-in-capsule form of IDE196
- Completed in-life portion of the ongoing 13-week GLP-compliant toxicology studies in two species, initiated in November 2019
- Interim data from the monotherapy arm of the Phase 1/2 basket trial on track for fourth quarter of 2020

- COVID-19 pandemic is not currently having a substantial impact, generally, on the ongoing IDE196 clinical program
    - GNAQ/11 patients enrolled in the ongoing Phase 1/2 clinical trial and sites affected by COVID-19 restrictions are adapting to logistical constraints on activities, such as travel and site visits
    - Patients are continuing on IDE196 therapy, which is an oral drug and is being shipped to and self-administered by patients at home
    - Patients are being monitored through a combination of telemedicine visits and local visits
    - Enrollment into the Phase 2 expansion arm for IDE196 as a monotherapy in non-MUM solid tumors having GNAQ or GNA11 hotspot mutations may be delayed by circumstances resulting from the COVID-19 pandemic. The specific impact is currently uncertain; two of four active sites for this arm of the clinical trial are continuing enrollment activities; the other two sites have suspended enrollment due to COVID-19.

- Preparing and on track for initiation of combination arm of the IDE196 Phase 1/2 clinical trial in mid-2020 to evaluate safety and efficacy of IDE196 in combination with binimetinib, a MEK inhibitor, in patients having tumors with activating GNAQ or GNA11 hotspot mutations, including in metastatic uveal melanoma and other solid tumors
    - Established Joint Development Committee with Pfizer to facilitate collaboration for combination arm drug supply, trial initiation and ongoing development
    - Coordinating with clinical trial sites to prepare for combination arm initiation
    - Preparation for combination arm of the clinical trial not currently substantially impacted by COVID-19

Preclinical Synthetic Lethality Programs

MAT2A

- Continuing preclinical development efforts of selected lead compound believed to favorably differentiate *in vivo* activity, physical properties and tolerability profile relative to published Agios compounds
- On track to select a development candidate in the second quarter of 2020
- Anticipate filing an IND for MAT2A inhibitor development candidate in fourth quarter of 2020

Pol Theta

- Targeting designation of Pol-theta inhibitor development candidate in second half of 2020

PARG

- Demonstrated in vivo proof of concept in a relevant animal model having a replication stress genetic signature

WRN

- Targeting to demonstrate *in vivo* proof of concept in relevant animal models in 2020

Corporate Updates

IDEAYA anticipates that existing cash, cash equivalents, and short-term and long-term marketable securities of $90.9 million (as of March 31, 2020) will be sufficient to fund planned operations into the end of 2021 to early 2022.

Our updated corporate presentation is available on our website, in the Presentations section of our Investor Relations page. See: https://ir.ideayabio.com/news-events/presentations.

Financial Results

As of March 31, 2020, IDEAYA had cash, cash equivalents, and short-term and long-term marketable securities totaling $90.9 million. This compared to cash, cash equivalents and short-term marketable securities of $100.5 million at December 31, 2019. The decrease was primarily due to cash used in operations.

Research and development expenses for the three months ended March 31, 2020 totaled $9.0 million compared to $8.0 million for the same period in 2019. The increase was primarily due to an increase in fees to CROs and CMOs as well as fees to contractors related to support costs for our Phase 1/2 clinical trial to evaluate IDE196 in solid tumors and the advancement of our lead product candidates through preclinical studies.

General and administrative expenses for the three months ended March 31, 2020 totaled $3.5 million compared to $2.1 million for the same period in 2019. The increase was primarily due to an increase in payroll expenses, including salaries, benefits and stock-based compensation expense related to increased general and administrative headcount to support our growth as a public company, and an increase in director and officer insurance policy premiums as a public company.

The net loss for the three months ended March 31, 2020 was $12.0 million compared to $9.6 million for the same period in 2019. Total stock compensation expense for the three months ended March 31, 2020 was $0.8 million compared to $0.4 million for the same period in 2019.

About IDEAYA Biosciences

IDEAYA is an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics for patient populations selected using molecular diagnostics. IDEAYA's approach integrates capabilities in identifying and validating translational biomarkers with small molecule drug discovery to select patient populations most likely to benefit from the targeted therapies IDEAYA is developing. IDEAYA is applying these capabilities across multiple classes of precision medicine, including direct targeting of oncogenic pathways and synthetic lethality – which represents an emerging class of precision medicine targets.

Forward-Looking Statements

This press release contains forward-looking statements, including, but not limited to, statements related to (i) timing of release of interim monotherapy data for the IDE196 Phase 1/2 basket trial, (ii) timing of the initiation of a combination clinical trial of

IDE196 and binimetinib, (iii) timing of selection of a development candidate and filing of an IND for a MAT2A inhibitor, (iv) timing of selection of a Pol-theta inhibitor development candidate, (v) timing for WRN demonstration of *in vivo* proof of concept in relevant animal models, and (vi) the extent to which IDEAYA's existing cash, cash equivalents, and short-term and long-term marketable securities will fund its planned operations. Such forward-looking statements involve substantial risks and uncertainties that could cause IDEAYA's preclinical and clinical development programs, future results, performance or achievements to differ significantly from those expressed or implied by the forward-looking statements. Such risks and uncertainties include, among others, the uncertainties inherent in the drug development process, including IDEAYA's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, IDEAYA's ability to successfully establish, protect and defend its intellectual property, the effects on IDEAYA's business of the worldwide COVID-19 pandemic, and other matters that could affect the sufficiency of existing cash to fund operations. IDEAYA undertakes no obligation to update or revise any forward-looking statements. For a further description of the risks and uncertainties that could cause actual results to differ from those expressed in these forward-looking statements, as well as risks relating to the business of IDEAYA in general, see IDEAYA's recent Quarterly Report on Form 10-Q filed on May 12, 2020 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

IDEAYA Biosciences, Inc.

Condensed S tatements of Operations and Comprehensive Loss

(*in thousands, except share and per share amounts*)

	Three Months Ended Mar 31,	
	2020	**2019**
Operating expenses		
Research and development	$ 9,026	$ 7,996
General and administrative	3,452	2,098
Total operating expenses	12,478	10,094
Loss from operations	(12,478)	(10,094)
Interest income and other income (expense), net	435	525
Net loss	$ (12,043)	$ (9,569)
Change in unrealized gains (losses) on marketable securities	(65)	39
Comprehensive loss	$ (12,108)	$ (9,530)
Net loss per share attributable to common stockholders,basic and diluted	$ (0.59)	$ (8.69)
Weighted average number of shares outstanding, basic and diluted	20,250,549	1,101,107

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands, except share and per share amounts*)

	March 31, 2020	December 31, 2019
Cash and cash equivalents and short-term and long-term marketable securities	$ 90,903	$ 100,482
Total assets	101,791	113,001
Total liabilities	12,688	12,601
Total liabilities and stockholders' equity	101,791	113,001

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For further information: Investor and Media Contact: IDEAYA Biosciences, Paul Stone, Chief Financial Officer, investor@ideayabio.com

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