IDEAYA Biosciences, Inc. Reports Fourth Quarter 2019 Financial Results and Provides Business Update

SOUTH SAN FRANCISCO, Calif., March 24, 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 fourth quarter ended December 31, 2019.

"IDEAYA is building a leading synthetic lethality biopharmaceutical company, advancing a broad pipeline of synthetic lethality programs, including our MAT2A program for which we have selected a lead compound MAT2A inhibitor. We also continue 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) mutations such as metastatic uveal melanoma (MUM), cutaneous melanoma and colorectal cancer, including evaluation of 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.

We continue to progress our MAT2A synthetic lethality program for tumors with MTAP deletion. We have selected a lead compound which we believe has favorably differentiated activity, physical properties and tolerability, and have scaled this lead compound for non-GLP toxicology studies in two species to support selection of a development candidate in the second quarter of 2020.

We also continue to progress our broad pipeline of synthetic lethality programs, including Pol theta for tumors with BRCA or other homologous recombination deficiency (HRD) mutations, Werner (WRN) for tumors with high microsatellite instability (MSI), and PARG for tumors with BRCA2 mutations, impaired base excision repair, or replication stress signature. We are applying our fully integrated research and translational capabilities to these programs. We have solved the crystal structures for each of these research programs, and we are conducting preclinical *in vivo* efficacy studies in three of our synthetic lethality programs.

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

Clinical Program IDE196

IDE196

- Advanced 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 March 15, 2020:
    - Enrolled 53 patients in IDE196 monotherapy arm of Phase 1/2 clinical trial
    - Ongoing evaluation of IDE196 monotherapy arm in MUM, with aggregate enrollment of 49 patients in the Phase 1 dose escalation and tablet formulation studies
    - Initiated the Phase 2 expansion for IDE196 as a monotherapy in solid tumors other than MUM having GNAQ or GNA11 hotspot mutations, with aggregate Phase 1/2 enrollment of 4 cutaneous melanoma patients
    - Selected 400mg BID (with one week 200 mg BID run-in) as Phase 2 monotherapy dose; observed higher average steady state exposure of free IDE196 (AUC_{free}, increase of approximately 44%) and higher trough concentration of IDE196 (C_{min}, increase of approximately 40%) at 400 mg BID relative to 300 mg BID dose

- Evaluating 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 targeted for second half 2020
- Entered into a clinical trial collaboration and supply agreement with Pfizer; targeting to initiate combination arm of 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
- Design and initiation of potential registration-enabling study in MUM will be evaluated based on results of ongoing IDE196 monotherapy arm and planned IDE196 / binimetinib combination arm of the Phase 1/2 clinical trial

Preclinical Synthetic Lethality Programs

MAT2A

- Observed single agent in vivo efficacy of our MAT2A inhibitors, including tumor growth inhibition or tumor regression in multiple MTAP -/- endogenous models
- Selected a lead compound which we believe has favorably differentiated *in vivo* activity, physical properties and tolerability profile relative to published Agios compounds
- Scaled the MAT2A lead compound for non-GLP toxicology studies in two species to support selection of a development candidate in the second quarter of 2020
- Expect to file an IND for MAT2A inhibitor development candidate in fourth quarter of 2020

Pol Theta

- Observed monotherapy activity, showing cell viability activity and *in vivo* tumor growth inhibition in a DLD1 BRCA2 -/- engineered model
- Observed combination activity with a PARPi, Olaparib, as well as synergistic cell viability activity and synergistic *in vivo* tumor growth inhibition in the DLD1 BRCA2 -/- engineered model, with a weak drug-drug interaction signal
- Targeting designation of Pol-theta inhibitor development candidate in second half of 2020

Werner (WRN)

- Observed dose-dependent cellular viability effect in multiple endogenous MSI high cell lines, with an expected lack of activity in microsatellite stable, or MSS, cell lines
- Observed dose-dependent cellular pharmacodynamic (PD) response in multiple endogenous MSI high cell lines
- Solved crystal structure of WRN helicase domain
- Targeting to demonstrate *in vivo* proof of concept in relevant animal models in 2020

PARG

- Observed dose-dependent cellular pharmacodynamic response and cellular viability effect in a HCC1806 XRCC1 -/- cell line
- Expanded research collaboration with Cancer Research UK (CRUK) and the University of Manchester, UK, to evaluate IDEAYA's potent selective PARG inhibitors *in vitro* and *in vivo* in multiple ovarian cancer cell lines and xenograft models, respectively, and to evaluate replication stress signature as a potential patient selection biomarker

"We continue to advance our programs, expand our capabilities and enhance our team. We believe that the IDE196 clinical program and our preclinical pipeline of synthetic lethality programs are maturing, moving forward toward our goal of improving lives through transformative precision medicines," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

Corporate Updates

IDEAYA anticipates that existing cash, cash equivalents, and short-term and long-term marketable securities of $100.5 million (as of December 31, 2019) 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 December 31, 2019, IDEAYA had cash, cash equivalents, and short-term and long-term marketable securities totaling $100.5 million. This compared to cash, cash equivalents and short-term marketable securities of $90.0 million at December 31, 2018. The increase was primarily due to the receipt of $50.2 million in net proceeds from IDEAYA's initial public offering, which was completed in May 2019, offset by cash used in operations.

Research and development expenses for the three months ended December 31, 2019 totaled $8.5 million compared to $7.6 million for the same period in 2018. The increase was primarily due to costs in connection with IDEAYA's Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, and costs for personnel and consulting in support of our research programs during the three months ended December 31, 2019.

General and administrative expenses for the three months ended December 31, 2019 totaled $2.8 million compared to $1.6 million for the same period in 2018. The increase was primarily due to an increase in costs for personnel and directors' and officers' liability insurance premiums in connection with becoming a publicly traded company.

Research and development expenses for the year ended December 31, 2019 totaled $34.3 million compared to $31.7 million for 2018. The increase was primarily due to an increase in costs in connection with IDEAYA's Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, and costs for personnel and consulting in support of our research programs during the year ended December 31, 2019, offset by a decrease in license fees for our IDE196 license agreement with Novartis during the year ended December 31, 2018.

General and administrative expenses for the year ended December 31, 2019 totaled $10.0 million compared to $4.7 million for 2018. The increase was primarily due to an increase in costs for personnel, directors' and officers' liability insurance premiums, and professional fees in connection with becoming a publicly traded company.

The net loss for the three months ended December 31, 2019 was $10.8 million compared to $8.6 million for the same period in 2018. Total stock compensation expense for the three months ended December 31, 2019 was $0.7 million compared to $0.3 million for the same period in 2018.

The net loss for the year ended December 31, 2019 was $42.0 million compared to $34.3 million for the same period in 2018. Total stock compensation expense for the year ended December 31, 2019 was $2.2 million compared to $1.0 million for the same period in 2018.

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 evaluation of initiation and design of potential registration-enabling study in MUM, (iv) timing of selection of a development candidate and filing of an IND for a MAT2A inhibitor, (v) timing of selection of a Pol-theta inhibitor development candidate, (vi) timing for WRN demonstration of *in vivo* proof of concept in relevant animal models, and (vii) 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 our 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 Annual Report on Form 10-K filed on March 24, 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 December 31,		Year Ended December 31,	
	2019	**2018**	**2019**	**2018**
Operating expenses				

Research and development	$ 8,541	$ 7,577	$ 34,319	$ 31,749
General and administrative	2,778	1,556	9,952	4,668
Total operating expenses	11,319	9,133	44,271	36,417
Loss from operations	(11,319)	(9,133)	(44,271)	(36,417)
Interest income	536	571	2,288	1,994
Other income (expense), net	2	—	8	77
Net loss	$ (10,781)	$ (8,562)	$ (41,975)	$ (34,346)
Change in unrealized gains (losses) on marketable securities	(13)	(14)	96	(30)
Comprehensive loss	$ (10,794)	$ (8,576)	$ (41,879)	$ (34,376)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.53)	$ (8.11)	$ (3.36)	$ (35.92)
Weighted average number of shares outstanding, basic and diluted	20,216,275	1,055,131	12,496,957	956,252

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

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

	December 31, 2019	**December 31, 2018**

Cash and cash equivalents and marketable securities	$ 100,482	$ 89,961
Total assets	113,001	96,541
Total liabilities	12,601	7,098
Total liabilities, redeemable convertible preferred stock and stockholders' equity	113,001	96,541

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https://media.ideayabio.com/2020-03-24-IDEAYA-Biosciences-Inc-Reports-Fourth-Quarter-2019-Financial-Results-and-Provides-Business-Update