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

- Initiated Phase 1 clinical trial for IDE397, a potential best-in-class MAT2A inhibitor for patients having tumors with MTAP-deletion
- Planning to present data at AACR in April 2021 for IDE397 (monotherapy efficacy in over forty PDX models with homozygous MTAP deletions across tumor types) and for PARG (monotherapy efficacy in CDX and PDX models based on defined biomarker)
- Hosting inaugural IDEAYA Synthetic Lethality Investor Day April 20, 2021 at 1:00 pm ET
- Targeting Development Candidates for PARG and Pol Theta programs in 2021
- Initiated dose expansion in the Phase 1/2 study of IDE196 / binimetinib combination in metastatic uveal melanoma (MUM) based on early clinical activity
- Targeting interim data for IDE196 / binimetinib combination in MUM and for IDE196 monotherapy in MUM and GNAQ/11-mutation skin melanoma in 2021, including tolerability, clinical efficacy, and survival data for IDE196 monotherapy

SOUTH SAN FRANCISCO, Calif., March 23, 2021 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq:IDYA), a synthetic lethality focused precision medicine oncology company committed to the discovery and development of targeted therapeutics, provided a business update and announced financial results for the fourth quarter ended December 31, 2020.

"In the last quarter, we have made important progress towards our goal to build a preeminent synthetic lethality-focused precision medicine oncology company, including advancing IDE397 into Phase 1 as a potential best-in-class MAT2A inhibitor to treat patients with MTAP-deletion, which represents approximately 15% of all solid tumors. We are also poised to expand our synthetic lethality pipeline, targeting Development Candidate nominations in 2021 for each of our potential first-in-class PARG and Pol Theta programs. Lastly, IDE196 has reached a key inflection point as we initiated dose expansion in our Phase 1/2 study evaluating the IDE196 / binimetinib combination in the GNAQ/11 mutation-driven cancer of metastatic uveal melanoma," said Yujiro S. Hata, Chief Executive Officer and President of IDEAYA Biosciences.

Program Updates
Key highlights for IDEAYA's pipeline programs include:

IDE397 (MAT2A)
IDEAYA is developing IDE397, a potent and selective small molecule inhibitor targeting methionine adenosyltransferase 2a (MAT2A), for solid tumors with methylthioadenosine phosphorylase (MTAP) deletions, a patient population estimated to represent approximately 15% of solid tumors. IDEAYA continues to lead research and development on the MAT2A program through early clinical development. Subject to exercise of its option, GSK will lead later stage global clinical development. Highlights:

- IDE397 investigational new drug application (IND) is effective for Phase 1 clinical trial evaluation of IDE397; targeting monotherapy First-Patient-In in first quarter of 2021;
- Clinical development plans for IDE397 include a dose escalation portion of the Phase 1 clinical trial in which IDEAYA plans to enroll patients having solid tumors with MTAP gene deletion. Patients will be identified by next generation sequencing (NGS) or by MTAP immunohistochemistry (IHC) assay with confirmatory NGS;
- Subject to satisfactory completion of the dose escalation portion of the Phase 1 clinical trial, IDEAYA plans to enroll MTAP deletion patients into one or more expansion arms in solid tumor indications selected based on preclinical data from a 40+ model PDX study and well as clinical development and commercial considerations;
- Planning to obtain patient biopsies from the dose escalation and expansion portions of the clinical trial for translational research, including evaluation of certain pharmacodynamic, or PD, biomarkers, such as peripheral S-adenosyl methionine (SAM), tumor SAM and tumor symmetric dimethylarginine (SDMA);

- Program objective to obtain preliminary clinical PD data from the dose-escalation portion of the IDE397 monotherapy Phase 1 clinical trial in the second half of 2021;
- Evaluating the preclinical efficacy of monotherapy IDE397 in over forty solid tumor patient derived xenograft (PDX) models with homozygous MTAP deletions across a range of solid tumor types. Preliminary results of this study show in vivo efficacy in multiple MTAP-null xenograft models when MAT2A is pharmacologically inhibited with IDE397 as monotherapy: we observed (a) tumor regressions, with >100% tumor growth inhibition, or TGI, in multiple PDX models across multiple solid tumor types, and (b) >75% TGI in approximately 50% of models and across major solid tumor types;
- Planning to present data summarizing the results of the IDE397 MTAP-deletion preclinical PDX panel study at the 2021 Annual Meeting of the American Association for Cancer Research (AACR) in April 2021;
- Planning to present preclinical data at AACR in April 2021 evaluating the effects of pharmacological inhibition of MAT2A, including analyses of genomic and metabolic effects in an isogenic cell pair and of proliferation effects in a panel of MTAP wild type and MTAP-deleted cell lines; and
- Preclinical combination tolerability and efficacy studies are ongoing to evaluate IDE397 in combination with GSK oncology assets as well as other potential oncology agents, such as taxanes, in preclinical studies.

PARG

IDEAYA is advancing preclinical research for an inhibitor of poly (ADP-ribose) glycohydrolase (PARG) in patients having tumors with a defined biomarker based on genetic mutations and/or molecular signature. Highlights:

- Demonstrated dose-dependent in vivo efficacy as monotherapy with tumor regression or stasis in multiple PDX models and in multiple cell-derived xenograft, or CDX, models. Observed tumor regressions (> 100% TGI) in multiple breast cancer PDX models with defined genetic and subtyping profiles. Observed tumor regressions and enhanced TGI relative to niraparib in multiple CDX models, including in vivo efficacy in a niraparib-resistant resistant CDX model;
- Planning to present data at AACR in April 2021 summarizing the results of preclinical studies evaluating the effects of pharmacological inhibition of PARG in a panel of homologous recombination deficient cell lines, and in CDX and PDX models; and
- Subject to further preclinical studies, IDEAYA is targeting to identify a PARG inhibitor development candidate in 2021.

Pol Theta

IDEAYA's DNA Polymerase Theta, (Pol Theta) program targets tumors with BRCA or other homologous recombination deficiency, or HRD, mutations. IDEAYA and GSK are collaborating on ongoing preclinical research, including small molecules and protein degraders, and GSK will lead clinical development for the Pol Theta program. Highlights:

- Demonstrated *in vivo* efficacy with tumor regression in BRCA2 -/- xenograft model with IDEAYA Pol Theta inhibitor in combination with niraparib, a GSK PARP inhibitor; and
- Subject to further preclinical studies, IDEAYA is targeting selection of a Pol Theta inhibitor development candidate in 2021.

Werner Helicase

IDEAYA is advancing preclinical research for an inhibitor targeting Werner Helicase for tumors with high microsatellite instability (MSI). IDEAYA and GSK are collaborating on ongoing preclinical research, and GSK will lead clinical development for the Werner Helicase program.

DNA Damage Targets

IDEAYA has initiated multiple preclinical synthetic lethality research programs, designated as DDT1 and DDT2, to identify small molecule inhibitors for DNA Damage Targets (DDT's) for patients with solid tumors characterized by

a proprietary biomarker or gene signature.

IDEAYA Synthetic Lethality Investor Day

IDEAYA is hosting an inaugural IDEAYA Synthetic Lethality Investor Day on April 20, 2020 at 1:00-3:00 pm ET with presentations from IDEAYA and GSK scientists, as well as renowned key opinion leaders. This event will be held in a virtual format; for additional information and registration see IDEAYA's website at: https://ir.ideayabio.com/events. Highlights:

- Scientific presenters include scientists from IDEAYA and GSK, and key opinion leaders Alan D'Andrea (Dana Farber Cancer Institute of Harvard Medical School) and Bill Sellers (Broad Institute of MIT and Harvard); and
- Topics will include an overview of Synthetic Lethality – an emerging area of precision medicine oncology, the GSK-IDEAYA strategic partnership, and IDEAYA's pipeline programs, including IDE397 clinical-stage program targeting MAT2A in MTAP-deleted tumors, Werner Helicase, a biologically-compelling synthetic lethality target, Pol Theta, a key target in MMEJ DNA Damage Repair pathway, and PARG, a novel target in a clinically validated pathway.

IDE196 (PKC)

IDEAYA continues to execute on its clinical trial strategy to evaluate IDE196 combination therapies in Metastatic Uveal Melanoma (MUM), including IDE196 / binimetinib and independently, IDE196 / crizotinib. The company is also evaluating IDE196 as monotherapy, with a focus in GNAQ/11-mutation skin melanoma. Based on preliminary IDE196 monotherapy clinical data and its mechanism of action, we anticipate IDE196 clinical activity independent of Human Leukocyte Antigen (HLA) status in GNAQ/11-mutation cancers.

IDE196 / Binimetinib Combination Therapy

IDEAYA is continuing patient enrollment into the IDE196 / binimetinib combination arm under the clinical trial collaboration and supply agreement with Pfizer. Highlights:

- Initiated dose expansion in the Phase 1/2 study evaluating the IDE196 / binimetinib combination in MUM based on early clinical activity, including percentage of patients with tumor reduction; targeting to enroll a total of approximately 40 patients in the IDE196 / binimetinib combination arm in MUM; and
- IDEAYA is anticipating interim data from the IDE196 / binimetinib combination therapy Phase 1/2 portion of the clinical trial in MUM patients in 2021, including tolerability and clinical efficacy.

IDE196 / Crizotinib Combination Therapy

IDEAYA is continuing patient enrollment into the IDE196 / crizotinib combination arm under the clinical trial collaboration and supply agreement with Pfizer. Highlights:

- Identified cMET as a potential biomarker and a cMET inhibitor as potential combination agent though translational research studies, including a retrospective analysis of human clinical samples from an IDE196 Phase 1 clinical trial, which supported cMET expression / activation as a potential biomarker / combination agent, and preclinical synergies between IDE196 and crizotinib in relevant cell models of a liver tumor; and microenvironment, a site of approximately 90% of uveal melanoma metastases; and
- Planning to present data summarizing the results of IDE196 cMET translational studies at AACR in April 2021.

IDE196 Monotherapy

IDEAYA is continuing enrollment into its ongoing Phase 1/2 basket trial evaluating IDE196 as monotherapy in patients having non-MUM tumors harboring GNAQ or GNA11 activating mutations. The company's development strategy in the monotherapy non-MUM GNAQ/11 arm of the clinical trial is focused on skin melanoma. Highlights:

- Preliminary clinical data from IDE196 monotherapy arm shows that IDE196 activity is independent of HLA status; and
- IDEAYA anticipates disclosing interim data from the monotherapy arm of its ongoing Phase 1/2 basket trial in 2021, including in MUM and in GNAQ/11-mutation skin melanoma, including tolerability, clinical efficacy, and survival data.

General

IDEAYA continues to monitor Covid-19 and its potential impact on clinical trials and timing of clinical data results. Initiation of clinical trial sites, patient enrollment and ongoing monitoring of enrolled patients, including obtaining patient computed tomography (CT) scans, may be impacted for IDEAYA clinical trials evaluating IDE397 and IDE196; the specific impacts are currently uncertain.

IDEAYA continues to enhance its leadership team with the addition of Matthew Maurer, M.D. as Vice President, Head of Clinical Oncology and Medical Affairs in January 2021. Dr. Maurer was previously with Bristol Myers Squibb, and was earlier an oncologist and Assistant Professor of Medicine at Columbia University College of Physicians and Surgeons.

Corporate Updates

IDEAYA's net losses were $34.5 million and $42.0 million for the years ended December 31, 2020 and December 31, 2019, respectively. As of December 31, 2020, the company had an accumulated deficit of $127.0 million.

As of December 31, 2020, IDEAYA had cash, cash equivalents and marketable securities of $283.6 million. IDEAYA supplemented its year-end cash, cash equivalents and marketable securities with an additional $43.3 million in aggregate gross proceeds received subsequent to year end from the sale and issuance of common stock under an at-the-market offering pursuant to the August 2020 Sales Agreement or the January 2021 Sales Agreement with Jefferies as sales agent (ATM Program).

IDEAYA believes that its cash, cash equivalents and marketable securities will be sufficient to fund our planned operations into 2024. These funds will support the company's efforts through potential achievement of multiple preclinical and clinical milestones across multiple programs

Our updated corporate presentation is available on our website, at our Investor Relations page: https://ir.ideayabio.com/.

Financial Results

As of December 31, 2020, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $283.6 million. This compared to cash, cash equivalents and short-term and long-term marketable securities of $100.5 million at December 31, 2019. The increase was primarily due to $100.7 million in net proceeds from IDEAYA's follow-on public offering, $100.0 million from the upfront payment received from GSK, $20.0 million in net proceeds from the private placement with GSK, and $6.6 million in net proceeds under the ATM Program received through December 31, 2020.

Collaboration revenue for the three months ended December 31, 2020 totaled $10.6 million compared to zero for the same period in 2019. Collaboration revenue was recognized for the performance obligations satisfied through December 31, 2020 under the GSK Collaboration Agreement.

Research and development (R&D) expenses for the three months ended December 31, 2020 totaled $12.1 million compared to $8.5 million for the same period in 2019. The increase was primarily due to manufacturing and clinical startup costs for IDE397, an increase related to our Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, an increase in fees to CROs, CMOs and external consultants related to the advancement of our lead product candidates through preclinical studies and increase in R&D headcount costs.

General and administrative (G&A) expenses for the three months ended December 31, 2020 totaled $3.8 million compared to $2.8 million for the same period in 2019. The increase was primarily due to an increase in G&A headcount costs, an increase in legal patent expense, and an increase in directors' and officers' liability insurance premiums.

The net loss for the three months ended December 31, 2020 was $5.1 million compared to $10.8 million for the same period in 2019. Total stock compensation expense for the three months ended December 31, 2020 was $1.0 million compared to $0.7 million for the same period in 2019.

The net loss for the year ended December 31, 2020 was $34.5 million compared to $42.0 million for the same period in 2019. Total stock compensation expense for the year ended December 31, 2020 was $3.6 million compared to $2.2 million for the same period in 2019.

About IDEAYA Biosciences

IDEAYA is a synthetic lethality focused precision medicine oncology 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 drug discovery to select patient populations most likely to benefit from its targeted therapies. IDEAYA is applying its research and drug discovery capabilities to 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) the timing of First-Patient-In and other development plans and timing for the Phase 1 clinical trial for IDE397, (ii) the various presentations at the 2021 Annual Meeting of AACR, (iii) the timing of identification of a development candidate for a PARG in inhibitor, (iv) the timing of identification of a development candidate for a Pol Theta inhibitor, (v) the timing and content of release of interim data for the IDE196/binimetinib combination arm of the Phase 1/2 GNAQ/11 basket trial, (vi) the timing and content of release of interim data for the IDE196 monotherapy arm of the Phase 1/2 GNAQ/11 basket trial, (vii) the impact of Copvid-19, and (viii) the extent to which IDEAYA's existing cash, cash equivalents, and 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 Annual Report on Form 10-K filed on March 23, 2021 and any current and periodic reports filed with the U.S. Securities and Exchange Commission.

IDEAYA Biosciences, Inc.

Condensed Statements of Operations and Comprehensive Loss

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

	Three Months Ended December 31,		Year Ended December 31,	
	2020	2019	2020	2019
Collaboration revenue	$ 10,571	$ —	$ 19,538	$ —
Total revenue	10,571	—	19,538	—
Operating expenses				
Research and development	12,051	8,541	39,698	34,319
General and administrative	3,800	2,778	15,184	9,952
Total operating expenses	15,851	11,319	54,882	44,271
Loss from operations	(5,280)	(11,319)	(35,344)	(44,271)
Interest income and other income (expense), net	145	538	849	2,296
Net loss	$ (5,135)	$ (10,781)	$ (34,495)	$ (41,975)
Change in unrealized gains (losses) on marketable securities	(28)	(13)	(58)	96
Comprehensive loss	$ (5,163)	$ (10,794)	$ (34,553)	$ (41,879)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.18)	$ (0.53)	$ (1.40)	$ (3.36)
Weighted average number of shares outstanding, basic and diluted	29,149,106	20,216,275	24,721,775	12,496,957

IDEAYA Biosciences, Inc.

Condensed Balance Sheet Data

(*in thousands*)

	December 31, 2020	December 31, 2019
Cash and cash equivalents and short-term and long-term marketable securities	$ 283,585	$ 100,482
Total assets	298,269	113,001
Total liabilities	99,995	12,601
Total liabilities and stockholders' equity	298,269	113,001

SOURCE IDEAYA Biosciences, Inc.

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

https://media.ideayabio.com/2021-03-23-IDEAYA-Biosciences-Inc-Reports-Fourth-Quarter-2020-Financial-Results-and-Provides-Business-Update