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

**- Single-arm Phase 2 clinical trial may be adequate to support an NDA seeking Accelerated Approval for IDE196 monotherapy in metastatic uveal melanoma (MUM)**
**- Targeting submission of a New Drug Application (NDA) to the FDA in fourth quarter of 2021 to first quarter of 2022 for IDE196 monotherapy in MUM**
**- Expect to file an IND for a differentiated MAT2A inhibitor development candidate in second half of 2020**
**- Cash, cash equivalents and short-term marketable securities of $109.4 million (as of September 30, 2019) anticipated to be sufficient to fund planned operations into third quarter of 2021**

SOUTH SAN FRANCISCO, Calif., Nov. 13, 2019 /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 third quarter ended September 30, 2019.

"We have made significant progress on our Phase 1/2 tissue-agnostic basket trial evaluating IDE196 in patients with solid tumors harboring GNAQ or GNA11 (GNAQ/11) mutations, including metastatic uveal melanoma (MUM), cutaneous melanoma and colorectal cancer. This clinical trial progress, considered together with recent FDA feedback providing guidance on the regulatory pathway for IDE196 for treatment of MUM, are important enabling steps to advance this clinical-stage program," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

IDEAYA continues to advance its MAT2A synthetic lethality program to treat patients having tumors with MTAP deletion. The Company remains committed to the research and development of a differentiated MAT2A inhibitor that could meaningfully enhance patient outcomes across a broad range of indications. IDEAYA also continues to progress its broad pipeline of synthetic lethality programs, including Pol theta for patients having tumors with BRCA or other homologous recombination deficiency (HRD) mutations, and Werner (WRN) for patients having tumors with high microsatellite instability (MSI).

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, which was initiated in June 2019 to evaluate IDE196 in solid tumors harboring activating GNAQ/11 mutations, and is entitled "*A phase 1/2 study of IDE196 in patients with solid tumors harboring GNAQ/11 mutations or PRKC fusions"* (ClinicalTrials.gov Identifier: NCT03947385)
    - Completed enrollment in the Phase 1 dose escalation portion of the Phase 1/2 clinical trial at sites in the U.S. and Australia
    - Anticipate selection of the dosing regimen and initiation of the Phase 2 portion of the clinical trial by year-end 2019
    - Expect to introduce a tablet formulation of IDE196 in Q1 2020 for use in the Phase 2 portion of the clinical trial
    - Enrolled our first cutaneous melanoma patient harboring a tumor with an activating GNAQ/GNA11 mutation in October 2019, a key milestone for evaluating IDE196 in solid tumors outside of metastatic uveal melanoma (MUM)
    - Expanded our relationship with Foundation Medicine, participating in their Smart Trials™ program for

identification of non-MUM patients having tumors with activating GNAQ/11 mutations for potential enrollment in our Phase 1/2 basket trial
    - Anticipate release of interim data from the Phase 1/2 basket trial in Q2/Q3 2020

- Obtained FDA feedback in End-of-Phase 1 meeting in Q4 2019, providing guidance on the regulatory pathway for IDE196 for treatment of MUM

    - Company's proposed single-arm Phase 2 IDE196-001 clinical trial may be adequate to support an NDA seeking Accelerated Approval for IDE196 monotherapy in metastatic uveal melanoma (MUM)
    - The single-arm potentially registration-enabling Phase 2 clinical trial will target enrollment of 60 evaluable MUM patients
    - The primary endpoint is overall response rate (ORR) as determined by blinded independent central review (BICR), supported by BICR-determined duration of response (DOR) as a secondary endpoint
    - The 13-week GLP-compliant toxicology studies in 2 species is scheduled to initiate in November 2019, in support of FDA requirement that study results be submitted prior to enrollment of more than approximately 50 patients in the investigational arm of the clinical trial that will support a marketing application

- Continued the ongoing Phase 1 clinical trial, entitled "*A Phase I, multi-center, open-label, study of LXS196, an oral protein kinase C inhibitor, in patients with metastatic uveal melanoma*" (ClinicalTrials.gov Identifier: NCT02601378), being conducted by Novartis

    - A confirmed Complete Response at the 200 mg BID dose level was observed at month 31 in one of four patients previously reported with confirmed Partial Response out of 30 total (28 evaluable) BID patients in this ongoing monotherapy arm of the Novartis clinical trial

- Based on confirmation of the single arm trial design and anticipated rate of enrollment, we are anticipating submission of a New Drug Application (NDA) to the FDA in Q4 2021 to Q1 2022 for IDE196 in MUM.

**Synthetic Lethality Preclinical Pipeline**

MAT2A

- We believe that data presented at the AACR/NCI/EORTC conference in October 2019 demonstrates clinical activity of MAT2A as a biological target in patients having tumors with MTAP deletion.
- Continuing our preclinical evaluation of potential drug candidates, including in the HCT116 engineered in-vivo model, and in multiple endogenous in-vivo models
- Goal is to select a MAT2A inhibitor development candidate in the first half of 2020 with differentiated properties relative to Agios' presented published compounds and Agios' publicly-disclosed properties of AG270
- Expect to file an IND for a differentiated MAT2A inhibitor development candidate in second half of 2020

"We continue to aggressively progress our programs, expand our capabilities and enhance our team.  IDEAYA remains committed to its vision of improving lives through transformative precision medicines, and believes that the IDE196 tissue-type agnostic basket trial and our pipeline of synthetic lethality programs are key elements of this goal," said Yujiro S. Hata, Chief Executive Officer and President at IDEAYA Biosciences.

**Corporate Updates**

IDEAYA anticipates that existing cash, cash equivalents and short-term marketable securities of $109.4 million (as of September 30, 2019) will be sufficient to fund planned operations into the third quarter of 2021.

**Financial Results**

As of September 30, 2019, IDEAYA had cash, cash equivalents and short-term marketable securities totaling $109.4 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 September 30, 2019 totaled $8.9 million compared to $12.5 million for the same period in 2018. The decrease was primarily due to license fees for our IDE196 license agreement with Novartis during the three months ended September 30, 2018, offset by an increase in costs in connection with IDEAYA's Phase 1/2 clinical trial to evaluate IDE196 in solid tumors, and costs for personnel, consulting, and laboratory supplies in support of our research programs during the three months ended September 30, 2019.

General and administrative expenses for the three months ended September 30, 2019 totaled $2.7 million compared to $1.1 million for the same period in 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 as well as external legal patent expenses for our product candidates.

The net loss for the three months ended September 30, 2019 was $11.0 million compared to $13.0 million for the same period in 2018. Total stock compensation expense for the three months ended September 30, 2019 was $0.5 million compared to $0.3 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) expected timing for dose selection for and initiation of the Phase 2 portion of the IDE196 Phase 1/2 basket trial, introduction of a tablet formulation of IDE196, release of interim data for the IDE196 Phase 1/2 basket trial, initiation of the 13-week GLP-compliant toxicology studies for IDE196, submission of an NDA to the FDA for IDE196 in MUM, selection of a MAT2A inhibitor development candidate and filing of an IND for a MAT2A inhibitor development candidate and (ii) the extent to which IDEAYA's existing cash, cash equivalents and short-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 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 November 13, 2019 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*)**

( ***Unaudited***)

| | Three Months Ended September 30, | | Nine Months Ended September 30, | |
|---|---|---|---|---|
| | **2019** | **2018** | **2019** | **2018** |
| Operating expenses | | | | |
| Research and development | $ 8,923 | $ 12,538 | $ 25,778 | $ 24,172 |
| General and administrative | 2,700 | 1,088 | 7,174 | 3,112 |
| Total operating expenses | 11,623 | 13,626 | 32,952 | 27,284 |
| Loss from operations | (11,623) | (13,626) | (32,952) | (27,284) |
| Interest income | 654 | 573 | 1,752 | 1,423 |
| Other income (expense), net | — | 1 | 6 | 77 |
| Net loss | $ (10,969) | $ (13,052) | $ (31,194) | $ (25,784) |
| Change in unrealized gains (losses) on marketable securities | 41 | 16 | 109 | (16) |

| | | | | |
|---|---|---|---|---|
| Comprehensive loss | $ (10,928) | $ (13,036) | $ (31,085) | $ (25,800) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.54) | $ (13.06) | $ (3.15) | $ (27.94) |
| Weighted average number of shares outstanding, basic and diluted | 20,158,223 | 999,369 | 9,895,574 | 922,664 |

**IDEAYA Biosciences, Inc.**

**Condensed Balance Sheet Data**

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

**(*Unaudited*)**

| | September 30, 2019 | December 31, 2018 (1) |
|---|---|---|
| Cash and cash equivalents and short-term marketable securities | $ 109,356 | $ 89,961 |
| Total assets | 122,331 | 96,541 |
| Total liabilities | 11,925 | 7,098 |
| Total liabilities, redeemable convertible preferred stock and stockholders' equity | 122,331 | 96,541 |

(1) Derived from the audited financial statements for the year ended December 31, 2018, included in the Company's Prospectus filed pursuant to Rule 424(b)(4) under the Securities Act with the U.S. Securities and Exchange Commission on May 24, 2019.

View original content to download multimedia:http://www.prnewswire.com/news-releases/ideaya-biosciences-inc-reports-third-quarter-2019-financial-results-and-provides-business-update-300957052.html

SOURCE IDEAYA Biosciences, Inc.

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

---

https://media.ideayabio.com/2019-11-13-IDEAYA-Biosciences-Inc-Reports-Third-Quarter-2019-Financial-Results-and-Provides-Business-Update