IDEAYA Announces IDE196 Program Update and Clinical Protocol Criteria Met for Cohort Expansion in Skin Melanoma for Phase 2 GNAQ/11 Basket Trial

- 4 evaluable GNAQ/11 mutation skin melanoma patients enrolled in Stage 1 cohort with a 100% Disease Control Rate (excluding 1 non-evaluable) and 1 confirmed partial response by RECIST 1.1 guidelines
- 15 additional skin melanoma patients harboring GNAQ/11 mutations will be enrolled in Stage 2 of cohort expansion in Phase 2 GNAQ/11 basket arm of the clinical trial
- Dosed first leiomyosarcoma patient in the Phase 2 GNAQ/11 basket arm, expanding the tissue-agnostic approach to additional solid tumors
- IDE196 tablet formulation complete and successfully introduced in ongoing clinical trial, including the IDE196-binimetinib combination arm and the GNAQ/11 basket arm
- 13-week preclinical toxicology studies in 2 species are now complete with receipt of submission-ready audited draft reports

SOUTH SAN FRANCISCO, Calif., July 16, 2020 /PRNewswire/ -- IDEAYA Biosciences, Inc. (Nasdaq: IDYA), an oncology-focused precision medicine company committed to the discovery and development of targeted therapeutics, announced that it has met the clinical protocol criteria for cohort expansion in the cutaneous (skin) melanoma cohort of its Phase 2 basket arm evaluating IDE196 monotherapy in solid tumors harboring GNAQ or GNA11 hotspot mutations (GNAQ/11).

IDEAYA has enrolled 4 evaluable and 1 non-evaluable skin melanoma patients harboring GNAQ/11 mutations in an initial Stage 1 cohort of the study design. Pursuant to the protocol, if no RECIST (Response Evaluation Criteria in Solid Tumors) responses are observed in the targeted 9 patients of Stage 1 cohort, no additional expansion patients are to be enrolled in that cohort; otherwise, a second Stage 2 of enrollment comprising of 15 additional patients may be enrolled for a total of 24 patients. The 1 confirmed partial response in a GNAQ/11 mutation skin melanoma patient was determined by RECIST guidelines (version 1.1).

"I am pleased IDE196 has met the criteria for Stage 2 expansion in skin melanoma, as these patients with GNAQ/11 mutations may not have actionable BRAF driver mutations and may also have a low tumor mutational burden, and thus be less responsive to existing treatment options," said Marlana Orloff, M.D., Assistant Professor at Thomas Jefferson University Hospital in Philadelphia, who is a Principal Investigator on the IDEAYA clinical trial.

IDEAYA continues to monitor Covid-19 and its potential impact on clinical trials and timing of clinical data results. Covid-19 infection rates have increased over the last weeks in several states in which our enrollment sites are located.

Based on the increased target enrollment and potential impact of the Covid-19 pandemic, further IDE196 monotherapy interim data is anticipated to be in the first half of 2021.

"IDE196 expansion in skin melanoma enables IDEAYA to build a larger data set and to explore potential combinations in this tumor type, and further validates our GNAQ/11 tissue-agnostic approach," said Mick O'Quigley, Vice President, Head of Development Operations at IDEAYA Biosciences.

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) enrollment of additional patients in Stage 2 of cohort expansion in Phase 2 GNAQ/11 basket trial, (ii) potential impact of Covid-19 on clinical trials and timing of clinical data results, and (iii) timing of IDE196 monotherapy interim data. 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 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.

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