Novartis highlights CTL019 data showing its potential in the treatment of specific types of hard-to-treat non-Hodgkin lymphoma

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- - Data show adult patients may achieve durable response rates, with 13 of 19 evaluable patients with relapsed/refractory non-Hodgkin lymphomas responding to therapy(1)
- - Recent milestones for Novartis CAR therapy program include initiation of global Phase II multi-center CTL019 study and activation of cell processing facility
- - Data also highlight preliminary safety and efficacy data for CTL019 in other indications

EAST HANOVER, N.J., June 1, 2015 /PRNewswire/ -- Novartis is highlighting data from an ongoing Phase II clinical study of CTL019, an investigational chimeric antigen receptor (CAR) T cell therapy, that indicate its potential in the treatment of specific types of hard-to-treat non-Hodgkin lymphoma. Findings from the ongoing study conducted by the University of Pennsylvania's Perelman School of Medicine (Penn) in adults with relapsed or refractory (r/r) diffuse large B-cell lymphoma (DLBCL) and follicular lymphoma (FL) found an overall response rate (ORR) of 100% in patients with FL and 50% in patients with DLBCL[1]. Thirteen of 19 evaluable patients responded to the therapy. Eleven achieved a complete response (CR) and two experienced a partial response (PR) to treatment[1]. These results will be presented in an oral session at the 51st American Society of Clinical Oncology (ASCO) Annual Meeting on Monday, June 1 (Abstract #8516, June 1, 3:24 p.m. CDT)[1].

"The results from this ongoing study of CTL019 are encouraging, as we now have data through six months showing that patients may have achieved durable overall response rates," said lead investigator Stephen Schuster, M.D., associate professor, division of Hematology/Oncology at the University of Pennsylvania, Abramson Cancer Center. "These data support our ongoing efforts to determine the potential role of CTL019 in improving outcomes for patients with certain types of B-cell lymphomas."

Study results include 19 adult patients (12 with DLBCL and seven with FL) who were evaluable for response[1]. The study found that six patients with a PR to treatment at three months achieved a CR by six months[1]. Two patients with a PR experienced disease progression at 6 and 12 months after treatment[1]. Median patient follow-up is 274 days for the patients with DLBCL and 290 days for the patients with FL[1]. In the study, two patients developed cytokine release syndrome (CRS) of grade 3 or higher at peak T cell expansion[1].

"These new CTL019 findings are inspiring as we continue clinical research with our collaborators at the University of Pennsylvania, with the goal of altering the course of cancer care and treating areas of critical unmet need," said Usman Azam, Global Head, Cell & Gene Therapies Unit, Novartis Pharmaceuticals. "As Novartis initiates the Phase II multi-center global study of CTL019, this reinforces our commitment to furthering the new frontier of cell and gene therapies."

Additional CTL019 data being presented at ASCO include the preliminary safety and efficacy findings of a Phase I study investigating the use of CTL019 in the treatment of multiple myeloma (Abstract #8517, June 1,

3:36 p.m. CDT)[2]. This study adds to the growing body of data on CARTs and supports the advancement of the expanding pre-clinical and early clinical research pipeline at Novartis.

Novartis has initiated a Phase II multi-center global study of CTL019 in pediatric patients with r/r acute lymphoblastic leukemia (ALL). This study has opened in the United States, with the intention of expanding into other countries as soon as possible. Further, Novartis has begun to process patient cells at its cell processing facility in Morris Plains, N.J., and will utilize the facility in the Phase II multi-center global study. The facility is the first US Food and Drug Administration (FDA)-approved Good Manufacturing Practices quality site for a cell therapy.

Novartis and Penn have an exclusive global collaboration to research, develop and commercialize CAR T cell therapies for the investigational treatment of cancers. In July 2014, the FDA designated CTL019 as a Breakthrough Therapy for the treatment of pediatric and adult patients with r/r ALL under the Penn Investigational New Drug application (IND). Breakthrough Therapy designation is intended to expedite the development and review of drugs that treat serious or life-threatening conditions if the therapy has demonstrated substantial improvement over an available therapy on at least one clinically significant endpoint. Novartis holds the worldwide rights to CARs developed through the collaboration with Penn for all cancer indications, including the lead program, CTL019.

About CTL019
CTL019 uses CAR technology to reprogram a patient's own T cells to "hunt" cancer cells that express specific proteins, called CD19. After they have been reprogrammed, the T cells (now called CTL019) are re-introduced into the patient's blood; they proliferate and bind to the targeted CD19+ cancer cells and potentially kill these tumor cells.

Because CTL019 is an investigational therapy, the safety and efficacy profile has not yet been established. Access to investigational therapies is available only through carefully controlled and monitored clinical trials. These trials are designed to better understand the potential benefits and risks of the therapy. Because of uncertainty of clinical trials, there is no guarantee that CTL019 will ever be commercially available anywhere in the world.

About Cytokine Release Syndrome
After CTL019 infusion, cytokine release syndrome (CRS) may occur when the engineered cells become activated and multiply in the patient's body resulting in the release of cytokines. During CRS, patients typically experience varying degrees of flu-like symptoms with high fevers, nausea, muscle pain, and in some cases, low blood pressure and breathing difficulties. CRS severity correlates with disease burden. Additionally, CRS also can occur in other non-CAR therapy settings including some monoclonal antibodies.

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The foregoing release contains forward-looking statements that can be identified by words such as "potential," "initiation," "ongoing," "will," "encouraging," "inspiring," "continue," "goal," "commitment," "growing," "initiated," "intention," "investigational," "Breakthrough Therapy," "intended," "yet," or similar terms, or by express or implied discussions regarding potential marketing approvals for CTL019, or regarding potential future revenues from CTL019. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management regarding future events, and are subject to significant known and unknown risks and uncertainties. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those set forth in the forward-looking statements. There can be no guarantee that CTL019 will be submitted or approved for sale in any market, or at any particular time. Nor can there be any guarantee that CTL019 will be commercially successful in the future. In particular, management's expectations regarding

CTL019 could be affected by, among other things, the uncertainties inherent in research and development, including unexpected clinical trial results and additional analysis of existing clinical data; unexpected regulatory actions or delays or government regulation generally; the company's ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected manufacturing issues, and other risks and factors referred to in Novartis AG's current Form 20-F on file with the US Securities and Exchange Commission. Novartis is providing the information in this press release as of this date and does not undertake any obligation to update any forward-looking statements contained in this press release as a result of new information, future events or otherwise.

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References

1. Schuster, Stephan J. et al. (1 June 2015). Phase IIa Trial of Chimeric Antigen Receptor Modified T Cells Directed Against CD19 (CTL019) in Patients with Relapsed or Refractory CD19+ Lymphomas [oral presentation]. 2015 American Society of Clinical Oncology Annual Meeting: Abstract 8516.
2. Garfall, Alfred L. et al. (1 June 2015). Safety and Efficacy of Anti-CD19 Chimeric Antigen Receptor (CAR)-Modified Autologous T Cells (CTL019) in Advanced Multiple Myeloma [oral presentation]. 2015 American Society of Clinical Oncology Annual Meeting: Abstract 8517.

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