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MEDIA & INVESTOR RELEASE

Novartis provides update on Phase III CANOPY-A study evaluating canakinumab as adjuvant treatment in non-small cell lung cancer

- *Phase III CANOPY-A trial did not meet primary endpoint of disease-free survival in patients with stages II-IIIA and IIIB completely resected non-small cell lung cancer*[1]
- *Findings will be presented at an upcoming medical meeting*
- *Novartis remains committed to pursuing new therapeutic options that can have a meaningful impact on the lives of people with lung cancer*

Basel, August 15, 2022 — Novartis announced today that the Phase III CANOPY-A study evaluating adjuvant treatment with canakinumab (ACZ885), an inhibitor of interleukin-1beta (IL-1β), in adult patients with stages II-IIIA and IIIB (T>5cm N2) completely resected (R0) non-small cell lung cancer (NSCLC) did not meet its primary endpoint of disease-free survival (DFS) versus placebo[1]. No unexpected safety signals were observed.[1] Findings from the trial will be presented at an upcoming medical meeting.

“We made an investment in the CANOPY program based on signals of reduced lung cancer incidence and mortality observed in the CANTOS study. These positive signals supported the study of canakinumab as adjuvant treatment for early lung cancer,” said Jeff Legos, Executive Vice President, Global Head of Oncology & Hematology Development, Novartis. “While we are disappointed CANOPY-A did not show the benefit we hoped for, every trial generates scientific evidence that supports future research and development, and we look forward to continuing to pursue new therapeutic options for people living with lung cancer, whose needs remain urgent and significant. We thank the patients and clinical investigators whose time and commitment made this research possible.”

CANOPY-A is a Phase III, multicenter, randomized, double blind study that is evaluating the efficacy and safety of canakinumab as adjuvant treatment in patients with NSCLC stages II-IIIA and IIIB (T>5cm N2), per American Joint Committee on Cancer/The Union for International Cancer Control (AJCC/UICC) 8th edition staging, whose margins are free of cancer following surgery[2]. In the trial, 1,382 patients were randomized 1:1 to canakinumab, 200 mg subcutaneously every three weeks, or matching placebo for up to one year[2]. Patients completed standard-of-care adjuvant cisplatin-based chemotherapy and radiation therapy, if applicable, prior to randomization[2].

About canakinumab (ACZ885)
Canakinumab is a human monoclonal antibody that binds with high affinity and selectivity to human IL-1β and inhibits IL-1β activity by blocking its interaction with its receptors[3-5]. By

inhibiting IL-1β, preliminary evidence suggests that canakinumab may suppress Pro-Tumor Inflammation to 1) enhance anti-tumor immune response; 2) reduce tumor cell proliferation, survival and invasiveness; and 3) impair angiogenesis[5]. Pro-Tumor Inflammation enables tumor development by driving cancer-causing processes and suppressing anti-tumor immune responses[6,7].

About the CANOPY program

Novartis launched the CANOPY study program after observing significantly lower than expected rates of lung cancer mortality among patients in the Phase III cardiovascular CANTOS trial. The CANTOS trial evaluated canakinumab as a secondary prevention measure for cardiovascular events in patients following a heart attack[5,8]. Patients in the CANTOS trial also were at high risk for inflammatory cancers like lung cancer due to advanced age, smoking history, and other clinical risk factors[5,8]. Based on these findings, Novartis launched three large-scale, randomized, Phase III clinical trials and a Phase II clinical trial to investigate canakinumab as a potential treatment option in NSCLC.

Novartis and lung cancer

Lung cancer is one of the most common cancers worldwide, accounting for more than 2 million new cases diagnosed each year[9]. More people die of lung cancer every year than any other cancer[9]. There are two main types of lung cancer—small cell lung cancer (SCLC) and non-small cell lung cancer (NSCLC)[10]. NSCLC accounts for approximately 85% of lung cancer diagnoses[11], and 30-55% of patients with early NSCLC develop recurrence despite resection[12].

Novartis is committed to working with the scientific and medical communities to reimagine the treatment of lung cancer and pursue advances in medicine that could extend the survival of people living with lung cancer. Novartis is developing experimental therapies that block cancer growth; learning more about ways to activate the body's immune system; increasing understanding of the relationship between chronic inflammation and tumor growth and progression; and exploring the potential for advanced nuclear medicine to fight the disease.

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This press release contains forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995. Forward-looking statements can generally be identified by words such as "potential," "can," "will," "plan," "may," "could," "would," "expect," "anticipate," "seek," "look forward," "believe," "committed," "investigational," "pipeline," "launch," or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. Such forward-looking statements are based on our current beliefs and expectations 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 the investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that such products will be commercially successful in the future. In particular, our expectations regarding such products could be affected by, among other things, the uncertainties inherent in research and development, including clinical trial results and additional analysis of existing clinical data; regulatory actions or delays or government regulation generally; global trends toward health care cost containment, including government, payor and general public pricing and reimbursement pressures and requirements for increased pricing transparency; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political, economic and business conditions, including the effects of and efforts to mitigate pandemic diseases such as COVID-19; safety, quality, data integrity or manufacturing issues; potential or actual data security and data privacy breaches, or disruptions of our information technology systems, 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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