



## NEWS RELEASE

# Compugen Announces FDA Clearance of IND for COM503 for the Treatment of Solid Tumors

7/29/2024

- FDA clearance triggers a \$30 million milestone payment from Gilead
- Company on track to initiate a Phase 1 trial for COM503, a differentiated antibody approach to harness cytokine biology for cancer therapeutics as monotherapy and in combination in advanced solid tumors in Q4 2024

HOLON, Israel, July 29, 2024 /PRNewswire/ -- **Compugen Ltd.** (Nasdaq: CGEN) (TASE: CGEN), a clinical-stage cancer immunotherapy company and a pioneer in computational target discovery, today announced that the U.S. Food and Drug Administration (FDA) has cleared the investigational new drug (IND) application to initiate a Phase 1 trial for COM503, a potential first-in-class, high affinity anti-IL-18 binding protein antibody licensed to Gilead Sciences, Inc. (Gilead). The IND clearance triggered a \$30 million milestone payment from Gilead and Compugen is on track to initiate the Phase 1 trial in solid tumors, in the fourth quarter of 2024.

"We are thrilled to receive FDA IND clearance for COM503 which triggers a \$30 million milestone payment from our partner Gilead, and the initiation of a Phase 1 trial will keep us on track to expedite COM503 development," said Anat Cohen-Dayag, Ph.D., President, and Chief Executive Officer of Compugen. "We are excited about the potential of COM503, a differentiated antibody approach to harness cytokine biology for cancer therapeutics which we discovered through our computational discovery work at Compugen."

Dr. Cohen-Dayag added, "This achievement reflects our track record in execution and diversity in our pipeline, adding another clinical program discovered through our predictive computational discovery engine. In addition, it further strengthens our balance sheet with an expected cash runway sufficient to take us into 2027. We look forward to the initiation of the Phase 1 trial in the fourth quarter of this year, for which our preparation is well-

advanced."

## About COM503 Phase 1 trial

The Phase 1 trial is a first-in-human, dose escalation and dose expansion trial to assess the safety and tolerability of COM503 as a monotherapy and in combination with Gilead's anti-PD-1, zimberelimab in participants with advanced or metastatic solid tumors globally.

## About the Compugen-Gilead license agreement

In 2023, Compugen and Gilead entered into a license agreement, pursuant to which Gilead was granted exclusive rights to develop and commercialize anti-IL-18 binding protein antibodies, including the COM503 drug candidate. Compugen is responsible for preclinical development and the anticipated first-in-human Phase 1 trial evaluating the safety and tolerability of COM503. Gilead will have the sole right to develop and commercialize COM503 thereafter. Gilead provided Compugen with a \$60 million upfront payment and will make a \$30 million payment for achievement of the milestone of IND clearance of COM503, the subject of this press release. Compugen will be eligible to receive up to an additional \$758 million in future development, regulatory and commercial milestone payments, with a total deal value of up to \$848 million. Compugen will also be eligible to receive single-digit to low double-digit tiered royalties on worldwide net sales.

## About Compugen

Compugen is a clinical-stage therapeutic discovery and development company utilizing its broadly applicable predictive computational discovery capabilities to identify new drug targets and biological pathways for developing cancer immunotherapies. Compugen has two proprietary product candidates in Phase 1 development COM701, a potential first-in-class anti-PVRIG antibody and COM902, a potential best-in-class antibody targeting TIGIT for the treatment of solid tumors. Rilvegostomig, a PD-1/TIGIT bispecific antibody where the TIGIT component is derived from Compugen's clinical stage anti-TIGIT antibody, COM902, is in Phase 3 development by AstraZeneca through a license agreement for the development of bispecific and multispecific antibodies. In addition, the Company's therapeutic pipeline of early-stage immuno-oncology programs consists of programs aiming to address various mechanisms of immune resistance, of which the most advanced program, COM503, a potential first-in-class, high affinity anti-IL-18 binding protein antibody, which has been granted IND clearance from the FDA, is licensed to Gilead. Compugen is headquartered in Israel, with offices in San Francisco, CA. Compugen's shares are listed on Nasdaq and the Tel Aviv Stock Exchange under the ticker symbol CGEN.

## Forward-Looking Statement

This press release contains "forward-looking statements" within the meaning of the Securities Act of 1933 and the Securities Exchange Act of 1934, as amended, and the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements are based on the current beliefs, expectations, and

assumptions of Compugen. Forward-looking statements can be identified using terminology such as "will," "may," "expects," "anticipates," "believes," "potential," "plan," "goal," "estimate," "likely," "should," "confident," and "intends," and similar expressions that are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Forward-looking statements include, but are not limited to, statements relating to our expectation to expedite COM503 development and that we are on track to initiate the Phase 1 trial in solid tumors in the fourth quarter of 2024, statements regarding our cash runway and statements relating to our expectation to receive the milestone payment from Gilead. These forward-looking statements involve known and unknown risks and uncertainties that may cause the actual results, performance, or achievements of Compugen to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. Among these risks: the general market, political and economic conditions in the countries in which Compugen operates, including Israel; and the effect of the evolving nature of the recent war in Gaza between Israel and Hamas. These risks and other risks are more fully discussed in the "Risk Factors" section of Compugen's most recent Annual Report on Form 20-F as filed with the Securities and Exchange Commission (SEC) as well as other documents that may be subsequently filed by Compugen from time to time with the SEC. In addition, any forward-looking statements represent Compugen's views only as of the date of this release and should not be relied upon as representing its views as of any subsequent date. Compugen does not assume any obligation to update any forward-looking statements unless required by law.

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