

MEDIA & INVESTOR RELEASE

Novartis expands targeted radioligand therapy pipeline with in-license for compounds targeting Fibroblast Activation Protein (FAP)

- *Expands Novartis Oncology radioligand pipeline with exclusive worldwide rights to develop and commercialize therapeutic applications for a library of FAP assets including FAPI-46 and FAPI-74*
- *Broad expression of FAP demonstrated in tumors or in tumor stroma across many solid tumors^{1,2,3}*
- *Novartis Oncology continues to reimagine cancer care through development of robust radioligand therapy portfolio*

Basel, March 30, 2021 — Novartis has obtained exclusive worldwide rights to develop and commercialize therapeutic applications for a library of Fibroblast Activation Protein (FAP) targeting agents including FAPI-46 and FAPI-74, through an assignment agreement with iTheranostics, Inc., an affiliate of SOFIE Biosciences, Inc. The FAP assets were originally developed at the University of Heidelberg. The agreement also includes co-exclusive rights for Novartis to develop imaging applications for these assets.

Fibroblast activation protein (FAP) is a cell-surface protein expressed at low levels in most normal adult tissues, but over-expressed in common cancers, particularly on cancer-associated fibroblasts that form the tumor stroma, which is essential for growth^{1,2,3,4}. High FAP expression on cancer-associated fibroblasts is generally associated with worse prognosis in solid tumors due to promotion of tumorigenesis and progression^{4,5,6,7}.

“We continue to invest in radioligand therapy as one of the four unique platforms of Novartis Oncology. We believe working across multiple approaches is the key to reimagining cancer care,” said Susanne Schaffert, PhD, President, Novartis Oncology. “FAP is an exciting target and these agents are a great fit with our radioligand therapy pipeline, which we are actively investigating across multiple tumor types. We believe this technology has the potential to transform many patients’ lives.”

Targeted radioligand therapy is a type of precision medicine combining two key elements: a targeting compound, or ligand, and a radioactive isotope, causing DNA damage that inhibits tumor growth and replication. These targeted drugs bind to markers or proteins over-expressed by certain tumors, or tumor-associated tissue, such as stroma. Due to the high-affinity of these agents for specific tumor cells or associated tumor tissue, surrounding healthy tissue is less affected.

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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,” “actively,” or similar terms, or by express or implied discussions regarding potential marketing approvals, new indications or labeling for the Fibroblast Activating Protein (FAP) targeting agents, including FAPI-46 and FAPI-74, or regarding potential future revenues from such FAP targeting agents. 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 FAP targeting agents, including FAPI-46 and FAPI-74, 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 the FAP targeting agents, including FAPI-46 and FAPI-74, will be commercially successful in the future. In particular, our expectations regarding the FAP targeting agents, including FAPI-46 and FAPI-74, 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.

About Novartis

Novartis is reimagining medicine to improve and extend people’s lives. As a leading global medicines company, we use innovative science and digital technologies to create transformative treatments in areas of great medical need. In our quest to find new medicines, we consistently rank among the world’s top companies investing in research and development. Novartis products reach nearly 800 million people globally and we are finding innovative ways to expand access to our latest treatments. About 110,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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