

## MEDIA & INVESTOR RELEASE

### Novartis presents important overall survival and quality-of-life results across solid tumor portfolio, among other key data at ESMO

- *New Kisqali® (ribociclib)\* overall survival (OS) results from MONALEESA-2 trial in HR+/HER2- advanced breast cancer patients in the first-line setting*
- *Health-related quality of life, pain and safety outcomes from phase III VISION trial of investigational radioligand therapy <sup>177</sup>Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer*
- *Data supporting upcoming regulatory filings for tislelizumab in people with squamous and non-squamous non-small cell lung cancer (NSCLC), and for alpelisib in people with PIK3CA-Related Overgrowth Spectrum (PROS)*
- *Novartis to host virtual panel on access to quality cancer care in Europe, open to ESMO registered participants, as part of the company's ongoing support for #EUnite initiative*

**Basel, August 30, 2021** — Novartis will present new data from its robust portfolio and pipeline of advanced therapeutic platforms in solid tumors, with more than 55 abstracts from Novartis-sponsored and investigator-initiated trials accepted at the upcoming European Society for Medical Oncology (ESMO) Congress 2021. The ESMO Congress will be held virtually September 16-21, 2021.

“At Novartis, we boldly push science further to make a meaningful difference to patients,” said Susanne Schaffert, PhD, President, Novartis Oncology. “With deeper analyses in overall survival and quality of life in breast and prostate cancer, as well as exciting research in other solid tumors, our data at ESMO demonstrates our ambition to transform lives and renew patients’ hope for the future.”

Key abstracts accepted by ESMO include:

- Overall survival (OS) results from the phase III MONALEESA-2 (ML-2) trial of postmenopausal patients with hormone receptor positive/human epidermal growth factor receptor 2 negative (HR+/HER2-) advanced breast cancer (ABC) treated with endocrine therapy (ET) ± ribociclib [Kisqali® (ribociclib)\*; Late-breaker abstract presentation # LBA17; Proffered paper session: Sunday, Sept. 19, 2:10 PM CEST]

- Association of quality of life (QoL) with OS in patients with HR+/HER2- ABC treated with ribociclib + ET in the ML-3 ML-7 trials [Kisqali; Abstract presentation # 233P; poster available: Monday, Sept. 13, 12:05 AM CEST]
- Health-related QoL, pain and safety outcomes in the phase 3 VISION study of <sup>177</sup>Lu-PSMA-617 in patients with metastatic castration-resistant prostate cancer (mCRPR) [Abstract presentation # 576MO; mini oral presentation: Sunday, Sept. 19, 5:50 PM CEST]
- EPIK-P1: Retrospective chart review study of patients with *PIK3CA*-related overgrowth spectrum (PROS) who have received alpelisib as part of a compassionate use programme [Late-breaker abstract presentation # LBA23; Proffered paper session: Friday, Sept. 17, 1:30 PM CEST]
- RATIONALE 304: Tislelizumab plus chemotherapy (chemo) vs chemo alone as first-line (1L) treatment for non-squamous (non-sq) non-small cell lung cancer (NSCLC) in patients who are smokers vs non-smokers [Abstract presentation # 1290P; poster available: Monday, Sept. 13, 12:05 AM CEST]
- RATIONALE 307: Tislelizumab plus chemo vs chemo alone as 1L treatment for advanced sqNSCLC in patients who were smokers vs non-smokers [Abstract presentation # 1297P; poster available: Monday, Sept. 13, 12:05 AM CEST]

Additional data presentations highlight the breadth of our pipeline and our ongoing commitment to discover and develop innovations that address unmet medical needs for patients with cancer:

| Medicine                                | Abstract Title                                                                                                                                                                               | Abstract Number                                                                       |
|-----------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------|
| <b>Prostate Cancer</b>                  |                                                                                                                                                                                              |                                                                                       |
| <sup>177</sup> Lu-PSMA-617              | PSMAddition: a phase 3 trial to compare treatment with <sup>177</sup> Lu-PSMA-617 plus standard of care (SOC) versus SOC alone in patients with metastatic hormone-sensitive prostate cancer | Abstract presentation # 647TiP<br>Poster available: Thursday, Sept. 16, 08:30 AM CEST |
| <sup>177</sup> Lu-PSMA-617              | PSMAfore: a phase 3 study to compare <sup>177</sup> Lu-PSMA-617 treatment with a change in androgen receptor pathway inhibitor in taxane-naïve patients with mCRPC                           | Abstract presentation #648TiP<br>Poster available: Thursday, Sept. 16, 08:30 AM CEST  |
| <b>Breast Cancer</b>                    |                                                                                                                                                                                              |                                                                                       |
| Piqray® (alpelisib)                     | Antineoplastic therapies after alpelisib or placebo + fulvestrant in patients with HR+/HER2-, PIK3CA-mutated ABC: an analysis from SOLAR-1                                                   | Abstract presentation # 309P<br>Poster available: Monday, Sept. 13, 12:05 AM CEST     |
| <b>Neuroendocrine Tumors (NET)</b>      |                                                                                                                                                                                              |                                                                                       |
| Lutathera® (lutetium Lu 177 dotatate)** | The phase 3 NETTER-1 study of <sup>177</sup> Lu-DOTATATE in patients with midgut neuroendocrine tumours: further survival analyses                                                           | Abstract presentation # 1102P<br>Poster available: Friday, Sept. 17, 09:00 AM CEST    |
| Lutathera                               | A phase II trial to evaluate the safety and dosimetry of <sup>177</sup> Lu-DOTA-TATE in adolescent patients with somatostatin                                                                | Abstract presentation # 1122TiP                                                       |

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receptor-positive  
gastroenteropancreatic neuroendocrine  
tumours, pheochromocytomas and  
paragangliomas

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Poster available: Friday, Sept.  
17, 09:00 AM CEST

With the unique opportunity to engage a variety of cancer care stakeholders in Europe, Novartis will also host an ESMO Industry Connect virtual panel on Monday, September 20, 8:00 AM CEST, under the #EUnite initiative, to discuss opportunities presented by the European Commission 'Europe's Beating Cancer Plan,' and practical steps to address inequalities in cancer care in the region. Featured panelists include:

- Bettina Ryll – Board Member of the European Commission's Cancer Mission, Physician and Founder of Melanoma Patient Network Europe
- Fatima Cardoso – Director Breast Unit, Champalimaud Clinical Centre; President, Advanced Breast Cancer Global Alliance
- John Ryan – EU Commission, Deputy Director General for Health

More information and access to the event will be available to all registered congress participants.

Additional details on Novartis-sponsored abstracts and activities, and access to the presentations will be available on <https://www.hcp.novartis.com/virtual-congress/esmo-2021/>, starting on September 16.

### **Product Information**

Approved indications for products vary by country and not all indications are available in every country. The product safety and efficacy profiles have not yet been established outside the approved indications. Because of the uncertainty of clinical trials, there is no guarantee that compounds will become commercially available with additional indications.

For full prescribing information, including approved indications and important safety information about marketed products, please visit <https://www.novartis oncology.com/news/product-portfolio>.

### **Disclaimer**

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.

### **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 109,000 people of more than 140 nationalities work at Novartis around the world. Find out more at <https://www.novartis.com>.

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\* Kisqali was developed by the Novartis Institutes for BioMedical Research (NIBR) under a research collaboration with Astex Pharmaceuticals.

\*\* Lutathera is a registered trademark of Advanced Accelerator Applications, a Novartis company.

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