## Investor Update



# Roche collaborates with Blueprint Medicines to bring a new treatment to people with RET-altered cancers

- Roche will obtain co-development and co-commercialisation rights for pralsetinib, an
  investigational, precision therapy in late-stage development for people with RET-altered nonsmall cell lung cancer, various types of thyroid cancer and other solid tumours.
- Blueprint Medicines and Roche will collaborate on the development of pralsetinib.
- Roche and Blueprint Medicines will co-commercialise pralsetinib in the US while Roche will be responsible for commercial activities outside the US, excluding Greater China\*.
- Roche will pay an upfront of \$675 million in cash in addition to a \$100 million equity investment in Blueprint Medicines who is eligible to receive up to \$927 million in potential milestones, plus royalties on net product sales outside the US.

Basel, 14 July 2020 - Roche (SIX: RO, ROG; OTCQX: RHHBY) and Blueprint Medicines Corporation (NASDAQ:BPMC), today announced the signing of a licensing and collaboration agreement providing exclusive rights to Roche for global co-development and commercialisation outside the United States (US), excluding Greater China\*. In the US, Genentech, a member of the Roche Group, will obtain co-commercialisation rights to pralsetinib, Blueprint Medicine's investigational, once-daily oral precision therapy for the treatment of people with RET-altered non-small cell lung cancer (NSCLC), medullary thyroid cancer (MTC) and other types of thyroid cancer, as well as other solid tumours. In addition, pralsetinib has demonstrated tumour-agnostic potential. The companies also plan to expand development of pralsetinib in multiple treatment settings and explore development of a next-generation RET inhibitor under the collaboration.

RET-activating fusions and mutations are key disease drivers in many cancer types, including NSCLC and MTC, and treatment options that selectively target these genetic alterations are limited. With the ongoing need for more targeted therapies that may offer clinical benefit to people with these types of cancers, this collaboration reflects Roche's strategy of providing treatments tailored specifically to a patient's individual tumour profile and delivering truly personalised healthcare.

In lung cancer, pralsetinib will complement Roche's broad portfolio of already approved medicines, alongside Alecensa, Rozlytrek, Tecentriq, Avastin and Tarceva and will further support our focus on understanding driver mutations in lung cancer through personalised treatment approaches. Beyond lung cancer, pralsetinib's tumour-agnostic potential further expands Roche's ongoing commitment to finding new approaches to treat cancer in a more personalised way based on the genetic mutation of the disease, irrespective of the tumour site of origin.

\* Greater China encompasses Mainland China, Hong Kong, Macau and Taiwan.

"We are very excited to enter into this collaboration with Blueprint Medicines, a partner we have already been working with for four years, with the goal of bringing a potentially transformative treatment option to patients with rare RET-altered cancers as quickly as possible," said James Sabry, Head of Roche Pharma Partnering. "In bringing pralsetinib to patients, we will leverage our global reach and expertise in oncology, as well as our capabilities in diagnostics and the use of real-world data toward our aim of providing personalised treatments for patients."

"With Roche's global reach and unparalleled expertise in personalised healthcare, this collaboration will accelerate our ability to bring pralsetinib to patients with significant medical needs around the world and expand development of pralsetinib across multiple treatment settings where there is potential to benefit even broader patient populations," said Jeff Albers, Chief Executive Officer of Blueprint Medicines.

Blueprint Medicines has submitted a new drug application (NDA) for pralsetinib to the US Food and Drug Administration (FDA) and a marketing authorisation application to the European Medicines Agency (EMA) for the treatment of RET fusion-positive NSCLC. The FDA granted priority review with an expected decision date of 23 November 2020. Blueprint Medicines has also submitted an NDA to the US FDA for RET mutation-positive MTC and RET fusion-positive thyroid cancer. The FDA has accepted the MTC application for its Real-Time Oncology Review (RTOR) pilot programme, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible.

Under the terms of the agreement, Blueprint Medicines will receive an upfront cash payment of \$675 million and a \$100 million equity investment in Blueprint Medicines' common stock. In addition, Blueprint Medicines is eligible to receive up to \$927 million in contingent development, regulatory and sales-based milestones, and royalties on net product sales outside the US. Roche and Blueprint Medicines will share global development expenses based on pre-specified cost-sharing percentages and equally share profits and losses in the US.

The closing of a minority portion of the equity investment is subject to the expiration or termination of the waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, and other customary closing conditions.

## **About RET-Altered Solid Tumours**

RET activating fusions and mutations are key disease drivers in many cancer types, including NSCLC and multiple types of thyroid cancer. RET fusions are implicated in approximately 1 to 2 percent of patients with NSCLC and approximately 10 to 20 percent of patients with papillary thyroid cancer, while RET mutations are implicated in approximately 90 percent of patients with advanced MTC. In addition, oncogenic RET alterations are observed at low frequencies in colorectal, breast, pancreatic and other cancers, and RET fusions have been observed in patients with treatment-resistant EGFR-mutant NSCLC.

## **About Pralsetinib**

Pralsetinib is an investigational, once-daily oral precision therapy designed to selectively target RET alterations, including fusions and mutations, regardless of the tissue of origin. Preclinical data have shown that pralsetinib potently inhibits primary RET fusions and mutations that cause cancer in subsets of patients, as well as secondary RET mutations predicted to drive resistance to treatment. Blueprint Medicines is developing pralsetinib for the treatment of patients with RET-altered NSCLC, various types of thyroid cancer and other solid tumours.

## **About Roche in Oncology**

Roche has been working to transform cancer care for more than 50 years, bringing the first specifically designed anti-cancer chemotherapy drug, fluorouracil, to patients in 1962. Roche's commitment to developing innovative medicines and diagnostics for cancers remains steadfast.

The Roche Group's portfolio of innovative cancer medicines includes: Alecensa® (alectinib); Avastin® (bevacizumab); Cotellic® (cobimetinib); Erivedge® (vismodegib); Gazyva®/Gazyvaro® (obinutuzumab); Herceptin® (trastuzumab); Kadcyla® (trastuzumab emtansine); MabThera®/Rituxan® (rituximab); Perjeta® (pertuzumab); Polivy® (polatuzumab vedotin-piiq); Tarceva® (erlotinib); Rozlytrek® (entrectinib); Tecentriq® (atezolizumab); Venclexta®/Venclyxto® (venetoclax); Xeloda® (capecitabine); Zelboraf® (vemurafenib). Furthermore, the Roche Group has a robust investigational oncology pipeline focusing on new therapeutic targets and novel combination strategies. For more information on Roche's approach to cancer, visit www.roche.com.

#### **About Roche in Personalised Healthcare**

For more than 20 years, Roche has helped lay the scientific groundwork for personalised healthcare with treatments that target the underlying biology of cancer and other diseases. Now, with profound changes in data and technology transforming how medicines are discovered, developed and delivered to patients, we are uniquely positioned to extend this approach across all of healthcare. With our ability to integrate research and development, personalised diagnosis, disease monitoring and treatment access, we are advancing personalised healthcare for every aspect of the patient experience.

Our strategy is rooted in groundbreaking science that can accelerate drug discovery and development. We are also leveraging technologies such as real-world datasets, artificial intelligence, genomic profiling and digital health across our therapeutic portfolio, with an initial emphasis on oncology, neurology, ophthalmology and diagnostics. Through collaborations with academic institutions, industry partners, patients, physicians and regulatory agencies, our goal is to dramatically improve the performance of the entire healthcare ecosystem and the lives of every patient.

## **About Roche**

Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics under one roof have made Roche the leader in personalised healthcare – a strategy that aims to fit the right treatment to each patient in the best way possible.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the eleventh consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2019 employed about 98,000 people worldwide. In 2019, Roche invested CHF 11.7 billion in R&D and posted sales of CHF 61.5 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit <a href="https://www.roche.com">www.roche.com</a>.

All trademarks used or mentioned in this release are protected by law.

## **Roche Investor Relations**

Dr. Karl Mahler Jon Kaspar Bayard Phone: +41 61 68-78503 Phone: +41 61 68-83894

e-mail: karl.mahler@roche.com e-mail: jon kaspar.bayard@roche.com

Dr. Sabine Borngräber Dr. Bruno Eschli

Phone: +41 61 68-88027 Phone: +41 61 68-75284

e-mail: <a href="mailto:sabine.borngraeber@roche.com">sabine.borngraeber@roche.com</a> e-mail: <a href="mailto:bruno.eschli@roche.com">bruno.eschli@roche.com</a>

Dr. Birgit Masjost Dr. Gerard Tobin

Phone: +41 61 68-84814 Phone: +41 61 68-72942

e-mail: <u>birgit.masjost@roche.com</u> e-mail: <u>gerard.tobin@roche.com</u>

## **Investor Relations North America**

Loren Kalm Dr. Lisa Tuomi

Phone: +1 650 225 3217 Phone: +1 650 467 8737 e-mail: <a href="mailto:kalm.loren@gene.com">kalm.loren@gene.com</a> e-mail: <a href="mailto:tuomi.lisa@gene.com">tuomi.lisa@gene.com</a>