



## Jazz Pharmaceuticals and Redx Announce Pan-RAF Inhibitor JZP815 to Enter Clinical Development

June 15, 2022

Clearance of IND application for JZP815 marks fifth Redx product candidate to enter clinical development and triggers USD \$5 million milestone payment from Jazz

Jazz to initiate clinical development of JZP815 as a drug candidate for several types of difficult-to-treat solid tumours

Dublin and Alderley Park, 15 June 2022, Jazz Pharmaceuticals (NASDAQ: JAZZ) and Redx (AIM: REDX) announce the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for JZP815, a pan-RAF inhibitor for the treatment of solid tumours and hematologic malignancies that contain mutations in the MAPK pathway, enabling Jazz to proceed with initiating a clinical trial for JZP815. As a result, a milestone payment of USD \$5 million from Jazz payable to Redx has been triggered.

The milestone payment was triggered under the Agreement in which Jazz acquired Redx's pan-RAF inhibitor programme, announced on 10 July 2019. Redx carried out development activities up to the completion of IND-enabling studies. Today's milestone is on top of USD \$6.5 million already received under the collaboration and Redx remains entitled to development, regulatory and commercial milestone payments as well as incremental tiered royalties in mid-single digit percentages, based on any future net sales.

Preclinical data from this pan-RAF programme was recently presented at the American Association for Cancer Research (AACR) conference in March. JZP815 is a precision pan-RAF inhibitor with a differentiated mechanism of action, and Jazz expects to assess its utility in treating several types of difficult-to-treat solid tumours where there remains significant unmet patient needs. Jazz expects to advance JZP815 into a Phase 1 clinical programme and, when initiated, JZP815 will be the fifth compound discovered by Redx to enter the clinic.

Lisa Anson, Chief Executive Officer of Redx, commented: "I am delighted that the IND application for the pan-RAF inhibitor, JZP815, has been accepted. When Jazz commence the clinical programme this will become the fifth drug candidate discovered by Redx to enter the clinic, further validating our world-class research and development capabilities. We value the strong relationship we have built with Jazz Pharmaceuticals and look forward to continuing our work together."

Rob Iannone, M.D., M.S.C.E., Executive Vice President, Global Head of Research and Development of Jazz Pharmaceuticals, commented: "We're excited to advance JZP815, a precision pan-RAF inhibitor with a differentiated mechanism of action, into a clinical trial programme. JZP815 may represent a significant advancement in the pan-RAF inhibitor class by not inducing paradoxical pathway activation that can stimulate the growth of certain cancers. The JZP815 programme exemplifies our continued progress in expanding our early-stage oncology pipeline, and in developing therapies with the potential to address unmet patient need. Redx has an exceptional team of research and development scientists and together we have formed an outstanding collaboration, leveraging the strengths of both companies."

Jazz and Redx also have a separate collaboration agreement to discover and develop drug candidates in the RAS-RAF-MAP kinase (MAPK) pathway, where Redx is again responsible for research and preclinical development activities up to IND application to the FDA.

### About Pan-RAF inhibitors

Mutations leading to uncontrolled signalling in the RAS-RAF-MAPK pathway are seen in around one third of all cancers. The Company's pan-RAF inhibitor programme aims to overcome resistance mechanisms associated with clinically approved B-RAF selective drugs.

The RAF kinases A-RAF, B-RAF and C-RAF are an integral part of the RAS-RAF-MAPK pathway, with B-RAF mutations commonly seen in the clinic. Although most B-RAF<sup>V600E/K</sup> mutant skin cancers are initially sensitive to approved B-RAF selective drugs, treatment resistance often develops leading to disease progression. Moreover, B-RAF<sup>V600E</sup> mutant colorectal cancers are surprisingly insensitive to these B-RAF selective drugs as single agents due to the compensatory functions of other RAF family members. Importantly, B-RAF selective therapies fail to show clinical benefit against the more prevalent RAS-mutated tumours.

### About JZP815

JZP815 is an investigational, pre-clinical stage pan-RAF kinase inhibitor that was discovered and developed using state-of-the-art screening methodologies and medicinal chemistry. JZP815 targets specific components of the mitogen-activated protein kinase (MAPK) pathway that, when activated by oncogenic mutations, can be a frequent driver of human cancer. JZP815 potently inhibits both monomer- and dimer-driven RAF signaling (e.g., RAS-induced), prevents paradoxical pathway activation induced by BRAF selective inhibition, and is active against class 1, class 2, and class 3 BRAF mutants, as well as BRAF fusions and CRAF mutants. JZP815 is not currently approved for use anywhere in the world. JZP815 is part of Jazz's growing early-stage R&D pipeline focused on solid tumours and targeted therapy.

### About Redx Pharma Plc

Redx Pharma (AIM: REDX) is a clinical-stage biotechnology company focused on the discovery and development of novel, small molecule, highly targeted therapeutics for the treatment of cancer and fibrotic diseases, aiming initially to progress them to clinical proof of concept before evaluating options for further development and potential value creation. Redx's lead oncology product candidate, the Porcupine inhibitor RXC004, commenced a Phase 2 programme in November 2021. The Company's selective ROCK2 inhibitor product candidate, RXC007, is in development for idiopathic pulmonary fibrosis and commenced a Phase 1 clinical trial in June 2021. Encouraging safety and pharmacokinetic data has been reported, and a Phase 2 clinical programme is confirmed to start in 2022. Redx's third drug candidate, RXC008, a GI-targeted ROCK inhibitor for the treatment of fibrostenotic Crohn's disease, is currently in pre-IND stage, with Phase 1 clinical studies expected to commence in 2023.

The Company has a strong track record of discovering new drug candidates through its core strengths in medicinal chemistry and translational science, enabling the Company to discover and develop differentiated therapeutics against biologically or clinically validated targets. The Company's accomplishments are evidenced not only by its two wholly-owned clinical-stage product candidates and rapidly expanding pipeline, but also by its

strategic transactions, including the sale of pirtobrutinib (RXC005, LOXO-305), a BTK inhibitor now in Phase 3 clinical development by Eli Lilly following its acquisition of Loxo Oncology and RXC006, a Porcupine inhibitor targeting fibrotic diseases including idiopathic pulmonary fibrosis (IPF), which AstraZeneca is progressing in a Phase 1 clinical study. In addition, Redx has forged collaborations with Jazz Pharmaceuticals with IND clearance for JZP815 and a further oncology programme in early stage research.

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**About Jazz Pharmaceuticals plc**

Jazz Pharmaceuticals plc (Nasdaq: JAZZ) is a global biopharmaceutical company whose purpose is to innovate to transform the lives of patients and their families. We are dedicated to developing life-changing medicines for people with serious diseases -often with limited or no therapeutic options. We have a diverse portfolio of marketed medicines and novel product candidates, from early-to late-stage development, in neuroscience and oncology. Within these therapeutic areas, we are identifying new options for patients by actively exploring small molecules and biologics, and through innovative delivery technologies and cannabinoid science. Jazz is headquartered in Dublin, Ireland and has employees around the globe, serving patients in nearly 75 countries. For more information, please visit [www.jazzpharmaceuticals.com](http://www.jazzpharmaceuticals.com) and follow @JazzPharma on Twitter.

The person responsible for the release of this announcement on behalf of Redx is Andrew Booth, Company Secretary.

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