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## **AstraZeneca and Ardelyx Announce Worldwide Licensing Deal For NHE3 Inhibitor Programme For Complications Of Renal Disease, Including Diabetes-Induced Renal Disease.**

AstraZeneca and Ardelyx today announced a worldwide exclusive licensing agreement for Ardelyx's NHE3 inhibitor programme, including the Phase 2-ready lead compound RDX5791, for the treatment of complications associated with end-stage renal disease

(ESRD) and chronic kidney disease (CKD). NHE3 is the sodium–hydrogen antiporter 3, a protein essential in the absorption of sodium in the intestines.

Ardelyx has evaluated RDX5791 in a Phase 2a clinical trial in constipation-predominant irritable bowel syndrome (IBS-C) and in two Phase 1 clinical studies in healthy subjects for its ability to divert sodium absorption in the gastrointestinal tract. Through its unique mechanism of action, RDX5791 is believed to decrease the absorption of dietary sodium and thus divert sodium excretion from the kidney (urine) to the faeces, sparing the kidney and the cardiovascular system from unhealthy exposure of both sodium and fluid accumulation. On this basis, the companies plan to develop RDX5791 for use in ESRD and CKD in addition to IBS-C, and intend to evaluate possible development in other diseases that are a consequence of sodium and fluid overload.

Under the terms of the agreement, AstraZeneca will pay \$35 million up front, with development milestones of \$237.5 million and milestones related to launch and commercialisation, as well as tiered, double-digit royalties. AstraZeneca will assume the subsequent development costs and Ardelyx will conduct clinical trials in Phase 2. As part of the transaction, Ardelyx has secured an option to co-promote the product in the US, subject to agreed limitations. Additional financial details were not disclosed.

"This licensing agreement accelerates our strong commitment to developing new medicines for people with renal complications, including those resulting from diabetes," said Gunnar Olsson, Vice President and Head of CVGI Innovative Medicines, AstraZeneca. "There is a significant unmet medical need to address the challenges caused by sodium and excess fluid in people with renal impairment. With a novel mechanism of action, RDX5791 has the potential to have a major impact on how doctors treat these patients. We are tremendously excited to join forces with the Ardelyx team and draw on their depth of knowledge and insight."

"We've been impressed with our interactions with AstraZeneca throughout this process and are confident with their commitment to develop this molecule successfully. AstraZeneca has been aggressive about pursuing novel medicines, making them among the best possible worldwide partners for validating Ardelyx's unique approach to drug development," commented Mike Raab, CEO of Ardelyx. "RDX5791 is our first clinical example of how our technology can be used to develop non-absorbed, small molecule therapeutics. We are delighted that AstraZeneca recognizes the potential of this compound."

### **NOTES TO EDITORS**

#### **About Ardelyx**

Ardelyx targets specific gut transporters and receptors with drugs that address important medical issues in cardiovascular disease, diabetes and chronic kidney disease. With its approach, Ardelyx has developed drug candidates that exhibit restricted absorption across

the gastrointestinal (GI) epithelia, thereby acting locally and specifically in the GI tract while avoiding systemic exposure and the potential for related systemic side effects. Until today, relatively few examples of non-systemic drugs have been developed and most of those are

based on polymeric binders; Ardelyx is pioneering novel non-systemic drugs based on small molecules which may require lower doses and exhibit improved drug properties.

The Company's lead product, RDX5791, a minimally-absorbed, orally administered NHE3 sodium transport inhibitor, is being developed both for constipation-predominant irritable bowel syndrome (IBS-C) and for prevention of sodium overload in patients with kidney and heart disease. Additionally, Ardelyx has other products in early development for type 2 diabetes and renal disease. To date, Ardelyx has raised \$56.0 million in venture and angel funding since it was founded in 2007. Ardelyx is located in Fremont, California. For more information, visit Ardelyx's website at [www.ardelyx.com](http://www.ardelyx.com).

#### **About AstraZeneca**

AstraZeneca is a global, innovation-driven biopharmaceutical business with a primary focus on the discovery, development and commercialisation of prescription medicines for gastrointestinal, cardiovascular, neuroscience, respiratory and inflammation,

oncology and infectious disease. AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. For more information please visit: [www.astrazeneca.com](http://www.astrazeneca.com)

## **ASTRAZENECA CONTACTS**

### **Media Enquiries UK**

Esra Erkal-Paler +44 20 7604 8030

Sarah Lindgreen +44 20 7604 8033

### **Media Enquiries Sweden**

Ann-Leena Mikiver +46 8 553 260 20

### **Investor Enquiries**

James Ward-Lilley +44 20 7604 8122 mob: +44 7785 432613

Karl Hård +44 20 7604 8123 mob: +44 7789 654364

Nicklas Westerholm +44 20 7604 8124 mob: +44 7585 404950

Ed Seage +1 302 886 4065 mob: +1 302 373 1361

## **ARDELYX CONTACTS**

### **Investor and Media Enquiries**

Mark Kaufmann +1 510-745-1751