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## Dr. Reddy's Laboratories announces entry into definitive agreement with BioDelivery Sciences International, Inc., to sell its U.S. and Canada territory rights for ELYXYB (celecoxib oral solution) 25 mg/mL

Hyderabad, India, August 04, 2021

For Immediate Release

**Hyderabad, India and Princeton, NJ, USA. August 04, 2021** - Dr. Reddy's Laboratories Limited (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY, hereafter known as "Dr. Reddy's"), announced today that it has entered into a definitive asset purchase agreement, pursuant to which Dr. Reddy's will sell its U.S. and Canada territory rights for ELYXYB (celecoxib oral solution) 25 mg/mL, to BioDelivery Sciences International, Inc. (BDSI).

Under the terms of agreement, Dr.Reddy's will receive U.S.\$6 million upfront upon closing followed by U.S.\$9 million one year from closing. Further, Dr. Reddy's is eligible to receive event based, sales based milestones and quarterly earn-out payments.

ELYXYB (previously known as DFN-15) is indicated for the acute treatment of migraine with or without aura in adults.

The closing of the transaction is subject to satisfactory completion of customary closing conditions including the applicable waiting period under the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (HSR Act), as amended.

**Erez Israeli, Chief Executive Officer of Dr. Reddy's Laboratories, said:** "ELYXYB reaffirmed our commitment to innovation and to develop meaningfully differentiated products that address significant unmet needs of patients. ELYXYB is an oral solution dosage form which makes it convenient for patients to take it immediately upon emergence of migraine attacks. Further, we are confident in BDSI's expertise and believe in their ability to realize the full potential of ELYXYB"

### INDICATION AND USAGE

ELYXYB is indicated in adults for the acute treatment of migraine with or without aura.

Limitations of Use:

- ELYXYB is not indicated for the preventive treatment of migraine.

## IMPORTANT SAFETY INFORMATION:

### WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

#### Cardiovascular Thrombotic Events

- **Nonsteroidal anti-inflammatory drugs (NSAIDs) cause an increased risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which can be fatal. This risk may occur early in the treatment and may increase with duration of use [see Warnings and Precautions (5.1) of Prescribing Information].**
- **ELYXYB is contraindicated in the setting of coronary artery bypass graft (CABG) surgery [see Contraindications (4) and Warnings and Precautions (5.1) of Prescribing Information].**

#### Gastrointestinal Bleeding, Ulceration, and Perforation

- **NSAIDs cause an increased risk of serious gastrointestinal (GI) adverse events including bleeding, ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms. Elderly patients and patients with a prior history of peptic ulcer disease and/or GI bleeding are at greater risk for serious (GI) events [see Warnings and Precautions (5.2) of Prescribing Information].**

ELYXB is contraindicated in patients with:

- Known hypersensitivity to celecoxib, any components of the drug product, or sulfonamides
- History of asthma, urticaria, or other allergic-type reactions after taking aspirin or other NSAIDs
- In the setting of CABG surgery

To minimize the potential risk for an adverse cardiovascular (CV) event in NSAID-treated patients, use ELYXYB for the fewest number of days per month as needed, based on individual treatment goals. Physicians and patients should remain alert for the development of such events, throughout the entire treatment course, even in the absence of previous CV symptoms. Patients should be informed about the symptoms of serious CV events and the steps to take if they occur.

Avoid the use of ELYXYB in patients with a recent myocardial infarction (MI) unless the benefits are expected to outweigh the risk of recurrent CV thrombotic events. If ELYXYB is used in patients with a recent MI, monitor patients for signs of cardiac ischemia.

NSAIDs, including ELYXYB, can cause serious gastrointestinal (GI) adverse events including inflammation, bleeding, ulceration, and perforation of the esophagus, stomach, small intestine, or large intestine, which can be fatal. These serious adverse events can occur at any time, with or without warning symptoms, in patients treated with celecoxib. Only one in five patients who develop a serious upper GI adverse event on NSAID therapy is symptomatic. Upper GI ulcers, gross bleeding, or perforation caused by NSAIDs occurred in approximately 1% of patients treated for 3 to 6 months, and in about 2% to 4% of patients treated for one year. However, even short-term NSAID therapy is not without risk.

Avoid the use of ELYXYB in patients with severe heart failure unless the benefits are expected to outweigh the risk of worsening heart failure. If ELYXYB is used in patients with severe heart failure, monitor patients for signs of worsening heart failure.

Elevations of ALT or AST (less than three times ULN) may occur in up to 15% of patients treated with NSAIDs, including ELYXYB.

Long-term administration of NSAIDs, including celecoxib, the active ingredient in ELYXYB, has resulted in renal papillary necrosis and other renal injury.

No information is available from controlled clinical studies regarding the use of celecoxib in patients with severe renal impairment. The renal effects of celecoxib may hasten the progression of renal dysfunction in patients with preexisting renal disease.

Overuse of acute migraine drugs (e.g., ergotamine, triptans, opioids, nonsteroidal anti-inflammatory drugs or combination of these drugs for 10 or more days per month), including ELYXYB, may lead to exacerbation of headache (medication overuse headache). Medication overuse headache may present as migraine-like daily headaches or as a marked increase in frequency of migraine attacks. Detoxification of patients, including withdrawal of the overused drugs and treatment of withdrawal symptoms (which often includes a transient worsening of headache) may be necessary.

NSAIDs, including ELYXYB, may increase the risk of bleeding events. Co-morbid conditions such as coagulation disorders or concomitant use of warfarin, other anticoagulants, antiplatelet drugs (e.g., aspirin), SSRIs, and serotonin norepinephrine reuptake inhibitors (SNRIs) may increase this risk.

Most common adverse reaction (at least 3% and greater than placebo) is dysgeusia.

These are not all the side effects associated with ELYXYB.

Please see Patient Information, Instructions For Use, Medication Guide and Full Prescribing Information for ELYXYB.

[https://www.accessdata.fda.gov/drugsatfda\\_docs/label/2021/212157s002lbl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/212157s002lbl.pdf)

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**About Dr. Reddy's:** Dr. Reddy's Laboratories Ltd. (BSE: 500124, NSE: DRREDDY, NYSE: RDY, NSEIFSC: DRREDDY) is an integrated pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - Pharmaceutical Services & Active Ingredients, Global Generics and Proprietary Products – Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars and differentiated formulations. Our major therapeutic areas of focus are gastrointestinal, cardiovascular, diabetology, oncology, pain management and dermatology. Dr Reddy's operates in markets across the globe. Our Major markets include – USA, India, Russia & CIS countries, and Europe. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

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**Disclaimer:** This press release may include statements of future expectations and other forward-looking statements that are based on the management's current views and assumptions and involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. In addition to statements which are forward-looking by reason of context, the words "may", "will", "should", "expects", "plans", "intends", "anticipates", "believes", "estimates", "predicts", "potential", or "continue" and similar expressions identify forward-looking statements. Actual results, performance or events may differ materially from those in such statements due to without limitation, (i) general economic conditions such as performance of financial markets, credit defaults, currency exchange rates, interest rates, persistency levels and frequency / severity of insured loss events (ii) mortality and morbidity levels and trends, (iii) changing levels of competition and general competitive factors, (iv) changes in laws and regulations and in the policies of central banks and/or governments, (v) the impact of acquisitions or reorganization, including related integration issues, and (vi) the susceptibility of our industry and the markets addressed by our, and our customers', products and services to economic downturns as a result of natural disasters, epidemics, pandemics or other widespread illness, including coronavirus (or COVID-19), and (vii) other risks and uncertainties identified in our public filings with the Securities and Exchange Commission, including those listed under the "Risk Factors" and "Forward-Looking Statements" sections of our Annual Report on Form 20-F for the year ended March 31, 2021. The company assumes no obligation to update any information contained herein."