Sandoz drives differentiated portfolio with deal to commercialize new treatment for Opioid-Induced Constipation in key European countries

- Agreement with Shionogi to commercialize Rizmoic® (naldemedine) in Germany, UK and Netherlands, plus right of first refusal for certain other European markets
- Rizmoic® is an innovative medicine for treating constipation caused by opioid pain relief medicines, in patients who have previously been treated with a laxative
- Agreement reinforces Sandoz anti-pain franchise and commitment to pioneer access to healthcare in areas of unmet medical need

HOLZKIRCHEN, April 11 2019 – Sandoz today announces that it has signed an agreement with Shionogi & Co Ltd for commercialization of Rizmoic® (naldemedine) in the key European markets of Germany, the UK and the Netherlands, plus right of first refusal for certain other European markets.

Rizmoic®, a once-daily 200-microgram oral tablet discovered and developed by Shionogi, is an innovative medicine indicated to treat opioid induced constipation (OIC) in adult patients previously treated with a laxative. Shionogi announced on February 22, 2019 that it had received EU marketing authorization for Rizmoic®.

OIC is a prevalent and distressing side-effect of opioid therapy that does not respond reliably to treatment with conventional laxatives1.

“Our purpose at Sandoz is to pioneer access by focusing increasingly on differentiated, value-added therapeutics that can make a real difference when it comes to meeting unmet medical needs,” said Francesco Balestrieri, Sandoz CEO a.i.

He added: “This agreement represents a significant step forward for that strategy and for patients in Europe, reinforcing our long-term commitment to building a leading anti-pain franchise and complementing our portfolio dedicated to minimizing the side-effects of opioid use.”

Sandoz has a strong presence in the European market for anti-pain therapeutics, as well as a complementary strategic focus on innovative therapeutic alternatives to combat opioid dependency. This year saw the US launch of two such products, including the first prescription digital therapeutic in this field.

Under the terms of the agreement, Sandoz will be responsible for commercializing Rizmoic® in Germany, the UK and the Netherlands and Shionogi will be responsible for its manufacturing and development. Further details of the deal are not being disclosed.

About Rizmoic® (naldemedine)
Naldemedine is a peripherally-acting mu-opioid receptor antagonist (PAMORA) that has been developed by Shionogi as a once-daily treatment for OIC. The efficacy and safety of naldemedine have been evaluated in randomized, double-blind, placebo-controlled studies in adult OIC patients in different countries who have chronic non-cancer pain or cancer. OIC is a change in bowel movements caused by opioid therapy that is characterized by any of the following: reduced bowel movement...
frequency, development or worsening of straining to pass bowel movements, a sense of incomplete rectal evacuation, or harder stool consistency\(^2\).

**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 “drives,” “portfolio,” “commitment,” “purpose,” “pioneer,” “focusing,” “can,” “step forward,” “strategy,” “commitment,” “launch,” “will,” “may,” “potential,” or similar terms, or by express or implied discussions regarding potential launches, marketing clearances and authorizations, new indications or labeling for naldemedine or the other products described in this press release, or regarding potential future revenues from such products or the collaboration with Shionogi. 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. You should not place undue reliance on these statements. There is no guarantee that the collaboration with Shionogi will achieve any or all of its intended goals and objectives, or within any particular time frame. Neither can there be any guarantee that naldemedine will be successfully launched in the defined European markets, in the expected time frame, or at all. Nor can there be any guarantee that naldemedine, the other products described in this press release, or the collaboration with Shionogi will be commercially successful in the future. In particular, our expectations regarding such products and the collaboration with Shionogi 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; the particular prescribing preferences of physicians and patients; competition in general, including potential approval of additional competing versions of such products; our ability to obtain or maintain proprietary intellectual property protection; litigation outcomes, including intellectual property disputes or other legal efforts to prevent or limit each of Sandoz or Shionogi from marketing its products; general political, economic and industry conditions; safety, quality or production 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 Sandoz**

Sandoz, a Novartis division, is a global leader in generic pharmaceuticals and biosimilars and a pioneer in the emerging field of prescription digital therapeutics. Our purpose is to pioneer access to healthcare by developing and commercializing novel, affordable approaches that address unmet medical need. Our broad portfolio of high-quality medicines, covering all major therapeutic areas and increasingly focused on value-adding differentiated medicines, accounted for 2018 sales of USD 9.9 billion. Sandoz is headquartered in Holzkirchen, in Germany’s Greater Munich area.

Sandoz is on Twitter. Sign up to follow @Sandoz global at [http://twitter.com/Sandoz_Global](http://twitter.com/Sandoz_Global).

**References**


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**Novartis Media Relations**
Central media line: +41 61 324 2200

E-mail: [media.relations@novartis.com](mailto:media.relations@novartis.com)

Eric Althoff
Novartis Global Media Relations
+41 61 324 7999 (direct)
+41 79 593 4202 (mobile)
[eric.althoff@novartis.com](mailto:eric.althoff@novartis.com)

Chris Lewis
Sandoz Global Communications
+49 174 244 9501 (mobile)
[chris.lewis@sandoz.com](mailto:chris.lewis@sandoz.com)

**Novartis Investor Relations**
Central investor relations line: +41 61 324 7944

E-mail: [investor.relations@novartis.com](mailto:investor.relations@novartis.com)

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065
Thomas Hungerbuehler +41 61 324 8425
Isabella Zinck +41 61 324 7188

North America
Richard Pulik +1 212 830 2448
Cory Twining +1 212 830 2417