AirFluSal® Forspiro® showed superiority at 12 months over Seretide® Diskus®\(^1\) in persistence to treatment

- New study shows that rate of patient persistence using Sandoz AirFluSal Forspiro is twice as high as for reference product Seretide® Diskus®.

- Study highlights importance of improving treatment "persistence" over time for long-term respiratory diseases.

- Analysis, published in leading medical journal, is largest European Real-World Evidence study ever conducted in asthma and COPD.

Holzkirchen, August 31, 2016 – New data just published in a leading medical journal shows for the first time that the rate of treatment persistence for patients using the innovative Sandoz AirFluSal Forspiro respiratory inhaler is more than twice as high as for the reference product. Persistence to treatment is defined as the duration of time from initiation to discontinuation of treatment\(^1\). Dr. Bruce Bender, the lead author on the paper, said: "COPD and asthma are long term diseases requiring long-term, persistent adherence to therapy. While adherence has been widely studied to date, a growing awareness of the large number of patients who abandon their asthma treatment suggests that persistence to treatment may be more relevant for longer-term outcomes."

Poor persistence to treatment rates are likely to result in poor outcomes including disease exacerbations, reduced quality of life, hospitalization, increased mortality, increased burden on the healthcare system and high economic costs\(^2,3,4\). Relatively few studies have investigated persistence in patients taking inhaled therapies, but those that have report sub-optimal rates in these patients\(^5,6,7\).

The results are reported in the latest edition of the leading Journal of Allergy and Clinical Immunology: In Practice. The comparative analysis study is the largest European Real-World Evidence (RWE) study ever conducted in asthma and COPD (chronic obstructive pulmonary disease).

The study, entitled "Comparative analysis of persistence to treatment among patients with asthma or COPD receiving AirFluSal® Forspiro® or Seretide® Diskus® salmeterol / fluticasone propionate combination therapy", concluded that patients using the Sandoz device showed a persistence rate of 22.9%, compared to 10.5% for those using the reference product device.

“These results fully validate our decision at Sandoz to develop our inhaler device in close collaboration with patients, incorporating their feedback”, said Dr. Spencer Jones, Sandoz Head of Global Medical Affairs, Respiratory. “This approach, which results in the device being effectively designed to give direct feedback to users, is the key to success in treating chronic conditions.”

---

\(^1\) Seretide® and Diskus® are registered trademarks owned by Glaxo Group Ltd.
He added: “What the data also highlight is the need for even more research to better understand patient persistence behaviors and to develop strategies to address what are still unacceptably low overall levels.”

The study was designed to retrospectively analyze persistence rates between the two devices, using dispensing data from a large German pharmacy database. While retrospective database analyses have some limitations, the strengths of this data include the fact that 11,744 patients were included in a matched pair analysis, controlled for gender, age and month of treatment initiation (to limit seasonal effects).

All patients were first time users of salmeterol/fluticasone propionate and persistence to treat was analyzed for a 12 month period.

**About AirFluSal Forspiro**

AirFluSal Forspiro offers the proven combination of salmeterol (a long-acting inhaled β2-agonist) and fluticasone propionate (an inhaled corticosteroid) in an innovative device. Safety, efficacy and equivalence have been proven in multiple clinical trials.

It was developed at Aeropharm GmbH in Rudolstadt, Germany, Sandoz’s global respiratory Center of Excellence. Sandoz collaborated with UK-based Vectura Group plc, a respiratory product development company, in the design and development of the product. The innovative and intuitive-to-use inhaler was invented at Vectura and its design was awarded the Red Dot Product Design award in 2011, an internationally recognized quality seal awarded by the Design Zentrum Nordrhein Westfalen in Essen, Germany.

In order to improve patient experience with inhalation devices, Sandoz and Vectura collaborated closely with patients during the development process. The device includes multiple feedback mechanisms such as visual control features, which help reassure the patient about dosing and a simple lever arm to load the dose.

AirFluSal Forspiro has been launched to date in approximately 30 countries, in Europe and elsewhere.

**Disclaimer**

This press release contains forward-looking statements that can be identified by terminology such as “long-term,” “persistent,” “growing,” “suggests,” “may,” “likely,” “strategies,” or similar terms, or by express or implied discussions regarding potential additional marketing approvals for AirFluSal Forspiro, or regarding potential future revenues from AirFluSal Forspiro. You should not place undue reliance on these statements. Such forward-looking statements are based on the current beliefs and expectations of management 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. There can be no guarantee that AirFluSal Forspiro will be submitted or approved for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that AirFluSal Forspiro will be commercially successful in the future. In particular, management’s expectations regarding AirFluSal Forspiro could be affected by, among other things, the uncertainties inherent in research and development, including unexpected regulatory actions or delays or government regulation generally; unexpected clinical trial results and additional analysis of existing clinical data; the company’s ability to obtain or maintain proprietary intellectual property protection; general economic and industry conditions; global trends toward health care cost containment, including ongoing pricing pressures; unexpected safety, quality or manufacturing issues, 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 as a result of new information, future events or otherwise.
About Sandoz
Sandoz is a global leader in generic pharmaceuticals and biosimilars. As a division of the Novartis Group, our purpose is to discover new ways to improve and extend people’s lives. We contribute to society’s ability to support growing healthcare needs by pioneering novel approaches to help people around the world access high-quality medicine. Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2015 sales of USD 10.1 billion. In 2015, our products reached more than 500 million patients and we aspire to reach one 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.

# # #

References


Novartis Media Relations
Central media line: +41 61 324 2200
E-mail: media.relations@novartis.com

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

Duncan Cantor
Sandoz Global Communications
+49 8024 476 2497 (direct)
+49 170 650 6067 (mobile)
duncan.cantor@sandoz.com

Chris Lewis
Sandoz Global Communications
+49 8924 476 1906 (direct)
+49 174 244 9501 (mobile)
chris.lewis@sandoz.com

Bernhard Schneider
Sandoz Global Communications
+49 8024 476 2594
bernhard.schneider@sandoz.com

Novartis Investor Relations
Central investor relations line: +41 61 324 7944
E-mail: investor.relations@novartis.com

Central
Samir Shah +41 61 324 7944
Pierre-Michel Bringer +41 61 324 1065

North America
Richard Pulik +1 212 830 2448
Sloan Pavsner +1 212 830 2417