NOVARTIS AG
Form 6-K
August 23, 2018

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER

PURSUANT TO RULE 13a-16 or 15d-16 OF

THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated August 23, 2018

(Commission File No. 1-15024)

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Novartis AG

(Name of Registrant)

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Switzerland

(Address of Principal Executive Offices)

_____

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: **No**:

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MEDIA RELEASE • COMMUNIQUE AUX MEDIAS • MEDIENMITTEILUNG

SOLAR-1 trial of Novartis investigational alpha-specific PI3K inhibitor BYL719 (alpelisib) meets primary endpoint in HR+/HER2- advanced breast cancer with PIK3CA mutation

- SOLAR-1 evaluated BYL719 plus fulvestrant vs. fulvestrant alone in HR+/HER2- advanced breast cancer patients with PIK3CA mutations who progressed on or following treatment with an aromatase inhibitor with or without a CDK4/6 inhibitor[1]

- *Approximately 40% of HR+ advanced breast cancer patients have PIK3CA mutations, and the PI3K pathway is the most commonly mutated pathway associated with tumor progression in HR+ advanced breast cancer*[2,3]

- *Full results will be submitted to an upcoming medical congress and Novartis will initiate discussions with regulatory authorities worldwide*

Basel, August 23, 2018 – Novartis today announced the global Phase III SOLAR-1 trial evaluating the investigational alpha-specific PI3K inhibitor BYL719 (alpelisib) has met the primary endpoint showing an improvement in progression-free survival (PFS). SOLAR-1 is evaluating BYL719 in combination with fulvestrant compared to fulvestrant alone in postmenopausal women and men with hormone-receptor positive, human epidermal growth factor receptor-2 negative (HR+/HER2-) PIK3CA-mutant advanced or metastatic breast cancer that progressed on or following aromatase inhibitor treatment with or without a CDK4/6 inhibitor[1].

“BYL719 is the only alpha-specific PI3K inhibitor and the first one to show potential increased benefit and acceptable tolerability for patients,” said Samit Hirawat, MD, Head, Novartis Oncology Global Drug Development. “We are encouraged by the results observed in the SOLAR-1 study and look forward to submitting the data to an upcoming medical congress and starting discussions with health authorities worldwide.”

Currently, there are no approved PI3K inhibitors for HR+ advanced breast cancer. The PI3K pathway plays an important role in regulating cell processes and is the most frequently altered pathway promoting tumor growth, disease progression and treatment resistance in HR+ advanced breast cancer[4,5].

Adverse events observed with investigational BYL719 in combination with fulvestrant in SOLAR-1 were generally consistent with those observed in previous BYL719 and fulvestrant studies[1]. The SOLAR-1 trial will continue to assess data for secondary endpoints. Novartis will begin discussions with global health authorities based on these results.

About PI3K inhibition in advanced breast cancer

Studies have established the role of PI3K signaling in several processes critical for cancer progression, including cell metabolism, growth, survival and motility[9]. Activation of the PI3K pathway in breast cancer is associated with resistance to endocrine therapy, disease progression and poorer prognosis[4,6].

Proteins in the PI3K pathway consist of four smaller parts called isoforms[7]. Approximately 40% of HR+ advanced breast cancer patients have genetic mutations that activate the alpha isoform, called PIK3CA mutations[2]. Mutations in the three other isoforms are typically not associated with advanced breast cancer[7].

About SOLAR-1

SOLAR-1 is a global, Phase III randomized, double-blind, placebo-controlled trial studying investigational BYL719 in combination with fulvestrant for postmenopausal women and men with PIK3CA-mutated HR+/HER2- advanced or metastatic breast cancer that progressed on or following prior aromatase inhibitor treatment with or without a CDK4/6 inhibitor[10].

The trial randomized 572 patients in a 1:1 ratio to receive continuous oral treatment with BYL719 300mg or placebo once daily in combination with fulvestrant 500mg intramuscular injections on days 1 and 15 on the first cycle and day 1 of each subsequent 28-day cycle as per fulvestrant prescribing information. Patients were allocated based on tumor tissue assessment to either a PIK3CA-mutant cohort or a PIK3CA non-mutant cohort. Stratification was based on visceral metastases and prior CDK4/6 inhibitor treatment[10].

The primary endpoint is PFS for patients with the PIK3CA mutation. Secondary endpoints include but are not limited to: overall survival, overall response rate, clinical benefit rate, health-related quality of life, efficacy in PIK3CA non-mutant cohort, safety and tolerability[10].

About BYL719 (alpelisib)

BYL719 is an investigational, orally bioavailable, alpha-specific PI3K inhibitor. In breast cancer cell lines harboring PIK3CA mutations, BYL719 has been shown to potentially inhibit the PI3K pathway and have antiproliferative effects. In addition, cancer cell lines with PIK3CA mutations were more sensitive to BYL719 than those without the mutation across a broad range of different cancers[11].

About Novartis in Advanced Breast Cancer

For more than 30 years, Novartis has been tackling breast cancer with superior science, great collaboration and a passion for transforming patient care. With one of the most diverse breast cancer pipelines and one of the largest numbers of breast cancer compounds in development, Novartis leads the industry in discovery of new therapies and combinations, especially in HR+ advanced breast cancer, the most common form of the disease.

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 “potential,” “can,” “will,” “expect,” “encouraged,” “upcoming,” “starting,” “look forward,” “investigational,” “pipeline,” “launch,” or simi by express or implied discussions regarding potential marketing approvals, new indications or labeling for BYL719 or the other investigational or approved products described in this press release, or regarding potential future revenues from such products. You should not place undue reliance on these statements. 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. There can be no guarantee that BYL719 or the other investigational or approved products described in this press release will be submitted or approved for sale or for any additional indications or labeling in any market, or at any particular time. Nor can there be any guarantee that BYL719 or such other products will be commercially successful in the future. In particular, our expectations regarding BYL719 and such other products 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; our ability to obtain or maintain proprietary intellectual property protection; the particular prescribing preferences of physicians and patients; general political and economic conditions; safety, quality or manufacturing 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 Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 125,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit http://www.novartis.com.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Novartis AG

Date: August 23, 2018 By: /s/ PAUL PENEPENT
Name: Paul Penepent
Title: Head Group Financial Reporting and Accounting