

阿斯利康

1. 日本卫生、劳动与福利部 (MHLW) 批准 Bevespi Aerosphere 用于治疗慢性阻塞性肺病 (COPD) 患者。

<http://tinyurl.com/y6zgunue>

Bevespi Aerosphere approved by the Japanese Ministry of Health, Labour and Welfare for patients with chronic obstructive pulmonary disease

First approval of a fixed-dose, long-acting dual bronchodilator in a pressurised metered-dose inhaler device in Japan

AstraZeneca today announced that *Bevespi Aerosphere* (glycopyrronium/formoterol fumarate) has been approved in Japan as a fixed-dose, long-acting dual bronchodilator to relieve symptoms in patients with chronic obstructive pulmonary disease (COPD).

This is the first approval by the Japanese Ministry of Health, Labour and Welfare for a maintenance fixed-dose, long-acting dual bronchodilator in a pressurised metered-dose inhaler (pMDI), which uses the innovative *Aerosphere* delivery technology.

The approval was based on positive results from the Phase III PINNACLE 4 trial,¹ which demonstrated the efficacy and safety of *Bevespi Aerosphere* in 1,756 patients with moderate to very severe COPD across Asia, Europe and the US, as well as the broader PINNACLE clinical programme involving more than 5,000 patients.^{2,3,4}

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: "As the first medicine in its class to be approved in a pressurised metered-dose inhaler in Japan, *Bevespi Aerosphere* offers an important new treatment option and choice of inhaler device for patients with moderate to very severe chronic obstructive pulmonary disease."

Bevespi Aerosphere is already approved in the US, EU, Canada, Australia and other countries as a dual bronchodilator for the maintenance treatment of moderate to very severe COPD.

2. Lynparza 在日本获批作为 BRCA 突变晚期卵巢癌的一线维持疗法。

<http://tinyurl.com/y3597rca>

Lynparza approved in Japan for 1st-line maintenance therapy in BRCA-mutated advanced ovarian cancer

60% of patients receiving Lynparza remained free of disease progression after three years vs. 27% receiving placebo in pivotal Phase III SOLO-1 trial

AstraZeneca and MSD's Lynparza is the only PARP inhibitor approved in Japan

AstraZeneca and MSD Inc., Kenilworth, N.J., US (MSD: known as Merck & Co., Inc. inside the US and Canada) today announced that *Lynparza* (olaparib) has been approved in Japan as a maintenance treatment after 1st-line chemotherapy in patients with BRCA-mutated (BRCAm) advanced ovarian cancer, as detected by an approved companion diagnostic test.

The approval by the Japanese Ministry of Health, Labour and Welfare was based on data from the pivotal Phase III SOLO-1 trial which tested *Lynparza* as maintenance monotherapy compared with placebo in patients with BRCAm advanced ovarian cancer following 1st-line platinum-based chemotherapy.

Dave Fredrickson, Executive Vice President, Oncology Business Unit, said: "This approval in Japan is a critical advance for women with ovarian cancer and a BRCA mutation. The goals of front-line therapy are long-term remission or a cure, yet currently 70% of patients relapse within three years of initial treatment. The progression-free survival benefit of *Lynparza* observed in SOLO-1 represents a major step forward in our ambition to transform patient outcomes."

百时美施贵宝

1. 百时美施贵宝今天宣布, Catalent 同意收购其在意大利 Anagni 的口服固体、生物制剂和无菌产品制造和包装设施。

<http://tinyurl.com/y2cm4tx4>

Catalent to Purchase Bristol-Myers Squibb Manufacturing Facility in Anagni, Italy

Bristol-Myers Squibb will maintain strategic presence in Italy through ongoing development and commercialization of new medicines

Catalent will continue to manufacture products for Bristol-Myers Squibb while offering other customers access to state-of-the-art sterile biologics fill/finish and oral solids manufacturing and packaging platforms

WEDNESDAY, JUNE 19, 2019 6:59 AM EDT

NEW YORK & SOMERSET, N.J.--(BUSINESS WIRE)--Bristol-Myers Squibb Company (NYSE:BMJ) and Catalent, Inc. (NYSE:CTLT), today announced that Catalent has agreed to purchase Bristol-Myers Squibb's oral solid, biologics, and sterile product manufacturing and packaging facility in Anagni, Italy. Catalent is the leading global provider of advanced delivery technologies, development and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. The companies anticipate completing the transaction by the end of 2019, subject to regulatory approvals, the information and consultation procedure with the unions, and the satisfaction of certain other customary closing conditions.

吉利德

1. Gilead 和 Nurix Therapeutics 建立战略合作，开发癌症和其他疾病的新疗法，将利用 Nurix 的专有药物开发平台识别消除特定靶标的新药物。

<http://t.cn/AiNgRJqa>

June 19, 2019

Gilead and Nurix Establish Strategic Collaboration to Develop Novel Therapies for Cancer and Other Diseases

– Collaboration will Leverage Nurix's Proprietary Drug Discovery Platform to Identify Novel Agents that Induce Degradation of Specified Drug Targets –

FOSTER CITY, Calif. & SAN FRANCISCO--(BUSINESS WIRE)--Jun. 19, 2019-- Gilead Sciences, Inc. (Nasdaq: GILD) and Nurix Therapeutics, Inc., a company discovering drugs that harness the body's natural process to control protein levels, today announced a global strategic collaboration to discover, develop and commercialize a pipeline of innovative targeted protein degradation drugs for patients with cancer and other challenging diseases.

百健

1. BIOGEN 将于 2019 年 7 月 23 日 (星期二) 公布 2019 年第二季度报告财务业绩。
<http://t.cn/AiNgEU3N>

BIOGEN TO REPORT SECOND QUARTER 2019 FINANCIAL RESULTS JULY 23, 2019

June 19, 2019 at 4:05 PM EDT

Cambridge, MA, -- [Biogen Inc.](#) (Nasdaq:BILB) today announced it will report second quarter 2019 financial results Tuesday, July 23, 2019, before the financial markets open.

Following the release of the financials, the Company will host a live webcast with Biogen management from 8:00-9:00 am ET. To access the live webcast, please go to the investors section of Biogen's website at <http://investors.biogen.com/>. Following the live webcast, an archived version of the call will be available on the website.