SANOFI

- Press Release -

Devastating blow for some English patients with advanced prostate cancer as life-extending drug Jevtana pulled from Cancer Drugs Fund

- **Removing Jevtana (cabazitaxel) means patients with hormone resistant advanced prostate cancer have been left with no treatment options following initial chemotherapy**

Guildford, England – 7 January 2015 – NHS England has shared that they are de-listing Jevtana (cabazitaxel) from the Cancer Drugs Fund (CDF), effective from March 2015. We understand a number of drugs of varying efficacy will also be removed from the CDF. However Jevtana fulfills an important unmet need in certain patients and has been proven to extend survival in advanced prostate cancer.[1] By de-listing this drug, NHS England is denying patients with few options access to a vital, life-changing treatment.

One in 20 men in the UK will die of prostate cancer.[2,3] In time, most prostate cancers become resistant to hormone therapy and continue to grow despite treatment.[4] Furthermore, for some men, the newer hormone treatments do not work.[5,6] Jevtana is the only active treatment for men with hormone resistant prostate cancer whose disease has progressed in spite of chemotherapy (with docetaxel),[1,5,6] and removing Jevtana from the CDF leaves these patients with no other treatment option. This de-listing goes against NHS England's own criteria that a drug should continue to be funded if there is no other effective treatment for a particular group of patients.

Dr. Alison Birtle, Consultant Clinical Oncologist, Lancashire Teaching Hospitals NHS Foundation Trust, is hugely disappointed at the Jevtana decision, "Prostate cancer is the most common male cancer in the UK, killing one man every hour. As a doctor who every day treats men with advanced prostate cancer, I am deeply saddened and my patients will be devastated by this decision. In my every day experience, Jevtana has given some men with advanced prostate cancer extra time – some of the men that I started to treat with Jevtana 3-4 years ago are still alive today – and most importantly this time has been of good quality, allowing them to carry on doing the things they enjoy despite their cancer. This decision is a travesty."

Sandy Tyndale-Biscoe, spokesperson for prostate cancer patients' charity Tackle, added, "In recent years, earlier diagnosis and better treatments have led to great improvements in the treatment of advanced prostate cancer and in survival. By removing a key treatment available for this group of patients who are resistant to hormone therapies, NHS England has failed to honour its commitment to people with cancer who have no other options."

Tarja Stenvall, General Manager of Sanofi in the UK, said, "We are hugely shocked and disappointed at this decision against Jevtana. We will do everything in our power to appeal this decision and are willing to hold open discussions to find a way forward so that patients still have access to this important medicine. The Government spoke of a commitment to improving patient access to cancer medicines and promised NICE reform to make this a reality, with the CDF in place until this happened. NICE,

the Department of Health and NHS England must quickly review and overhaul the evaluation process for cancer drugs, as promised."

In addition Zaltrap®▼ (aflibercept), a novel treatment that extends life in the later stages of metastatic colorectal cancer (mCRC),[7] has also been de-listed from the CDF. Previously rejected by NICE in England yet deemed cost effective in Scotland by the Scottish Medicines Consortium (SMC),[8] there is a call for NICE to re-evaluate their decision as rapidly as possible to avoid a postcode lottery across the UK. Zaltrap is also under review for use in Wales by the All Wales Medicines Strategy Group (AWMSG).[9]

Dr. Rob Glynne-Jones, Lead Clinician in Gastrointestinal Cancer at Mount Vernon Hospital and Chief Medical Advisor of Bowel Cancer UK, commented, "As a cancer specialist, it is extremely disappointing to find that you cannot use the tools of your trade – that is, effective anticancer drugs, which in some circumstances can also improve the patient's chance of long-term survival. It is even more disappointing to find that this option has now been taken away from you. Aflibercept's de-listing significantly narrows patient choice which in turn will widen the gap in survival for UK patients with colorectal cancer compared with the rest of the world."

Nick Bason, Head of Policy and Communications, Bowel Cancer UK commented: "We are disappointed by the decision NHS England has made to de-list Zaltrap from the Cancer Drugs Fund. It is imperative that people with advanced bowel cancer have access to treatment options that their clinicians feel that they would benefit from. This will be a blow for patients and their families and highlights the unequal access to treatment for people with advanced bowel cancer across the UK, given that the authorities in Scotland have deemed Zaltrap to be a cost-effective treatment."

Tarja Stenvall also commented, "We call on NICE to re-evaluate their negative appraisal of Zaltrap as quickly as possible to give English bowel cancer patients the same treatment options as those in Scotland."

Colorectal, or bowel cancer, is a major killer. After lung cancer it is responsible for the greatest number of male and female cancer deaths in the UK.[10] In its registration trial, Zaltrap increased the number of patients surviving to two years from 18.7% to 28.0%[7] and is the only biologic for colorectal cancer to receive approval from a health technology assessment body for its licensed indication. It is inconceivable that NHS England should de-list this medicine. By doing so, some bowel cancer patients in this country will die prematurely.

There have been 1,154 and 707 requests submitted to the CDF for Zaltrap and Jevtana respectively in the last 18 months,[11] and both of these medicines are available to prostate and bowel cancer patients in other European countries. Countries including Ireland, France, Germany, Spain and Italy – some of which are under much greater financial pressure than the UK – have allowed their patients to benefit from these treatments.

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The CDF has played a key role in providing innovative cancer therapies to those needing them most, delivering benefits to more than 55,000 people since it was introduced in 2010.[12] Yet these recent changes have not taken into account the opinions of those on the frontline of patient care. A recent survey of oncology clinicians found that 95% had recently applied for CDF funding, yet over half were unsure or did not know about the re-evaluation consultation.[13] Removing drugs at short notice may cause uncertainty and confusion for clinicians and patients, and prevent healthcare professionals from prescribing the medicines they feel are in the best interests of their patients.

- ENDS -

Notes to Editors

Prostate cancer

Prostate cancer is the most common male cancer in the UK; in the UK one in eight men will get prostate cancer during their lives.[14] Over 40,000 men are diagnosed with prostate cancer each year.[14]

Most men with advanced prostate cancer eventually become resistant to hormonal therapy[15] and their disease can progress after docetaxel chemotherapy. Before Jevtana, multiple medicines had been tested in this area without success demonstrating that this is a very difficult to treat population.[15]

Jevtana

Jevtana is a novel taxane (plant-based) chemotherapy that may be active in cancer cells which are resistant to standard chemotherapy.[16,17] Jevtana works by inhibiting cell division causing cancer cell death.[16]

Jevtana is the only treatment for hormone resistant prostate cancer following progression on docetaxel to extend life versus an active comparator.[1,5,6] It has been licensed in the UK and the rest of Europe for use in men with advanced prostate cancer and available on the CDF since 2012.

Colorectal cancer

If diagnosed early, colorectal cancer is highly treatable but only 9% of patients in the UK are diagnosed at the very earliest stage of the disease.[18] Metastatic or advanced colorectal cancer is a difficult-to-treat disease with limited treatment options and poor outcomes.[19] The goal is now targeted therapy which aims for high efficacy but with reduced side effects.[20]

Zaltrap

Zaltrap is a targeted biologic agent with a novel mode of action. It is an anti-angiogenic that works in a different way to other available treatments for mCRC licensed for use in the UK.[21]

When Zaltrap is administered in combination with FOLFIRI it is proven to increase overall survival, progression free survival and the overall response rate in patients with metastatic colorectal cancer previously treated with an oxaliplatin-containing treatment.[7]

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Cancer Drug Fund

The Cancer Drugs Fund (CDF) was set up as an interim measure by the coalition Government to facilitate better access to cancer drugs. Drugs on the CDF list are those that either haven't yet been approved by the National Institute for Health and Care Excellence (NICE) and aren't available within the NHS in England, or following appraisal haven't been deemed cost effective.[22]

The CDF will run until the end of March 2016 when a new way of setting prices for cancer drugs, which aims to make more drugs routinely available in the NHS, will be introduced.

- The CDF has delivered benefits for more than 55,000 patients since it was introduced in 2010[12]
- The CDF provides access to 43 different medicines in 80 different indications[23]
- 42 indications were re-evaluated by NHS England in December 2014[24]
- From March 2015, delisted medicines will no longer be available on the NHS
- Bowel cancer drugs were accessed over 5,000 times via the CDF in 2013/14, accounting for one quarter of all drugs during that time[25]

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About Sanofi Oncology

Based in Cambridge, Massachusetts, USA and Vitry, France, Sanofi Oncology is dedicated to translating science into effective therapeutics that address unmet medical needs for cancer and organ transplant patients. Starting with a deep understanding of the disease and the patient, Sanofi Oncology employs innovative approaches to drug discovery and clinical development, with the ultimate goal of bringing the right medicines to the right patients to help them live healthier and longer lives. We believe in the value of partnerships that combine our internal scientific expertise with that of industry and academic experts. Our portfolio includes 10 marketed products and more than 15 investigational compounds in clinical development, including small molecules and biological agents.

About Sanofi

Sanofi, a global and diversified healthcare leader, discovers, develops and distributes therapeutic solutions focused on patients' needs. Sanofi has core strengths in the field of healthcare with seven growth platforms: diabetes solutions, human vaccines, innovative drugs, consumer healthcare, emerging markets, animal health and the new Genzyme. Sanofi is listed in Paris (EURONEXT: SAN) and in New York (NYSE: SNY).

Sanofi Forward Looking Statements

This press release contains forward-looking statements as defined in the Private Securities Litigation Reform Act of 1995, as amended. Forward-looking statements are statements that are not historical facts. These statements include projections and estimates and their underlying assumptions, statements regarding plans, objectives, intentions and expectations with respect to future financial results, events, operations, services, product development and potential, and statements regarding future performance. Forward-looking statements are generally identified by the words "expects", "anticipates", "believes", "intends", "estimates", "plans" and similar expressions. Although Sanofi's management believes that the expectations reflected in such forward-looking statements are reasonable, investors are cautioned that forward-looking information and statements are subject to various risks and

uncertainties, many of which are difficult to predict and generally beyond the control of Sanofi, that could cause actual results and developments to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. These risks and uncertainties include among other things, the uncertainties inherent in research and development, future clinical data and analysis, including post marketing, decisions by regulatory authorities, such as the FDA or the EMA, regarding whether and when to approve any drug, device or biological application that may be filed for any such product candidates as well as their decisions regarding labelling and other matters that could affect the availability or commercial potential of such product candidates, the absence of guarantee that the product candidates if approved will be commercially successful, the future approval and commercial success of therapeutic alternatives, the Group's ability to benefit from external growth opportunities, trends in exchange rates and prevailing interest rates, the impact of cost containment policies and subsequent changes thereto, the average number of shares outstanding as well as those discussed or identified in the public filings with the SEC and the AMF made by Sanofi, including those listed under "Risk Factors" and "Cautionary Statement Regarding Forward-Looking Statements" in Sanofi's annual report on Form 20-F for the year ended December 31, 2011. Other than as required by applicable law, Sanofi does not undertake any obligation to update or revise any forward-looking information or statements.

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