December 16, 2019

Alemtuzumab (Campath/MabCampath): New safety information

Dear Healthcare Professional,

Sanofi would like to inform you about new safety information that has been identified from post-marketing use with alemtuzumab. This was identified for Campath/MabCampath (alemtuzumab) (hereafter referred to as "Campath") in relation to safety evaluations conducted for Lemtrada (alemtuzumab) in the multiple sclerosis (MS) indication. Due to their differing dosing and indications for use, Campath and Lemtrada are considered to have distinct safety profiles. As such, separate product information is maintained for each product.

Newly identified safety information

The new safety information for Campath includes post-marketing reports of haemophagocytic lymphohistiocytosis (HLH), stroke (including ischaemic and haemorrhagic stroke), glomerulonephritis, thyroiditis, hypothyroidism and hyperthyroidism. As a risk minimization measure, the Campath prescribing information will be updated to include these events in the "Adverse Events" section in addition to the information on HLH in the "Warnings" section as shown below.

Haemophagocytic lymphohistiocytosis (HLH)
During postmarketing use, HLH has been reported in patients treated with Campath. HLH is a life-threatening syndrome of pathologic immune activation characterized by clinical signs and symptoms of extreme systemic inflammation. It is associated with high mortality rates if not recognized early and treated. Symptoms have been reported to occur within a few months following the initiation of treatment, commonly observed in association with infections. Patients who develop early manifestations of pathologic immune activation should be evaluated immediately, and a diagnosis of HLH should be considered.

Potential impacts on the Campath Access Program

In countries where Sanofi maintains marketing authorization for Campath, it is indicated for use as a single agent for the treatment of B-cell chronic lymphocytic leukemia (B-CLL). Globally, prescribers may also receive Campath for a number of additional indications, including HLH, via the Campath Access Program. This program, including the impact of off label use on the safety profile of Campath, has been under review. Sanofi will issue follow-up communication if this review yields any additional significant updates.

Call for reporting

Healthcare professionals are encouraged to report adverse events in patients treated with Lemtrada or Campath.

To report adverse events in connection with the use of Campath, please use Individual Safety Information form and the email address for AE reporting in your country that can be found on ([Clinigen] https://cliniport.co.uk/; [Lash] https://www.campathproviderportal.com/.)

Company contact point

For further information please contact:

Clinigen:

- Tel: +44 (0) 1283 494 340
- Fax: +44 (0) 1283 494 341

LASH:

- Telephone: +1 877.422.6728
- Fax: +1 800.513.1824