Call with the CoVig-19 Alliance of Plasma Manufacturers 3 July

A call was held with the Alliance to get an update on progress on their Covid-19 convalescent plasma derived medicinal product aiming to treat Covid-19.

Participants:

Consortium: [redacted] (Takeda), [redacted] (Takeda), [redacted] (CSL Behring), [redacted] (CSL Behring), [redacted] (Takeda), [redacted] (CSL Behring), [redacted] (CSL Behring), [redacted] (Takeda), [redacted] (CSL Behring)

SANTE: [redacted]

Presentation of the Alliance

After a short 'tour de table', a presentation of the Alliance was made. The Alliance was founded by Takeda and CSL Behring who have been joined by Octpharma, LFB, Biotest, and Biopharma as members. There are also contributors and supporters who have different expertise outside of core development of the plasma product i.e. IT skills. The idea is to develop a hyper-immunoglobulin (HiG) from convalescent plasma to combat Covid-19. It is called Covig-19. The Alliance believe it can be one of first treatments available given previous experience developing HiG products.

The Alliance has been formed to take advantage of collective expertise to develop a non-branded product which will be of benefit to greatest number of patients as possible. There are three clear goals of working together: 1. To accelerate development, 2. To improve the chance of success of the clinical trial 3. To increase supply and availability of the finished product.

Development of the HiG

The difference between HiG and transfusion of convalescent plasma was explained. The specifications for the manufacturing process are the same as for other products, just the source material will be different. The previous safety record (for other immunoglobulins) can thus be used to show safety. Currently working with small volumes of low 100s of litres and plan is to go into 1000s of litres.

Clinical trials and regulatory aspects

The Alliance explained that a University of Minnesota-led trial (Insight #013) is the only trial to be used for the Marketing Authorisation application. HiG is to be provided by 4 manufacturers including two outside of the Alliance (Grifols and BioEmergence). 30 sites around the world with 9 in Europe will be involved in the trial. The plan is to treat 500 patients – 250 per arm, who will receive 400mg doses in a single infusion. The Alliance plans to submit a Scientific Advice package this week and the first patient could be treated in early August. After the clinical trials additional manufacturers could be added and clinical data would be made available to them. There would be individual registrations for MA. Members of the Alliance will be used to provide the source plasma. They hope to finish the trial by Q4 and have marketing authorisation in Q1 next year. Success of the programme will depend on ability to collect CCP – the Alliance consider this this is the biggest challenge and concern and called on the Commission to help facilitate access to this. Most plasma collected for trial has so far therefore been collected in the US (1000s of litres). The Alliance might come back for support to increase EU collection. The Alliance also mentioned need and plans to work on some ethical principles on the future global distribution of the HiG therapy.

SANTE B4 gave an overview of the action it had already taken in conjunction with EMA to mitigate the decreases in overall plasma collection in the US and EU Member States.

It was agreed that a further update on progress of the clinical trial would be given in September.