Neutralising antibodies for safer organ transplants

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Serious complications can arise following kidney transplants. If dialysis is required within the first seven days, then the transplanted organ is said to have a Delayed Graft Function (DGF), and essentially been rejected by the body's immune system. The risk of DGF increases the longer the blood supply has been cut off from the kidney.

While there is currently no specific treatment for DGF, an EU-funded project entitled MABSOT has developed a novel drug – OPN-305 – which can reduce both the incidence and severity of this condition. The project, completed in September 2014, could lead to safer, more

effective surgical procedures and thus healthier patients.

During trials, OPN-305 was given to patients about to undergo kidney transplants. Antibodies – proteins in our body that adhere to objects our immune systems do not recognise – can sometimes react adversely to transplanted organs. When inflammation caused by specific proteins called TLR2 receptors is triggered as a response to a newly transplanted kidney, this can lead to DGF. This serious complication affects over half of those who receive kidneys from deceased donors.

What OPN-305 does is target these naturally-occurring proteins responsible for initiating an inflammatory reaction (the body's natural response to injury or infection). By blocking these TLR2 receptors, OPN-305 helps to mediate the immune system's response to organ transplants, and thus help prevent the onset of DGF. Initial clinical trials have shown that the drug is safe, with 50 medical centres in the US and Europe and 270 patients involved.

In addition to bringing significant benefits to patients, the MABSOT project will also boost Europe's pharmaceutical industry. Developing new drugs can be a time consuming and extremely expensive process, which is why it was important that OPN-305 achieved what is known as 'orphan' designation from regulators. This means that the developers of the drug will benefit from a number of incentives, including scientific advice and market exclusivity once the medicine is on the market.

To qualify for orphan designation, a medicine must be intended for the treatment, prevention or diagnosis of a disease that is life-threatening or chronic and it must be unlikely that marketing the medicine would generate sufficient returns to justify the investment needed for its development. In other words, the application must be for a drug to treat a fairly rare disease.

Applications are examined by the European Medicines Agency's Committee for Orphan Medicinal Products (COMP), using the network of experts that the Committee has built up.

Accelerated approval means that the MABSOT team has been able to move through the development process quicker than they would have without gaining orphan drug designation. Furthermore, the medicine could also have applications for other organ transplants, such as lung, heart or pancreatic transplantation, and even for other diseases, including cancer and rheumatoid arthritis. MABSOT received nearly EUR 6 million in EU funding and was coordinated by Opsona Therapeutics in Ireland.

More information: www.mabsot.eu/

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