

IMMUNOGENIC VACCINE AGAINST THE HCV AND/OR HBV

Market

In accordance with WHO report „Progress report on access to hepatitis C treatment” dated March 2018 population of people currently infected with HCV virus amounts to ca. 71 million worldwide. High treatment costs and poor HCV detection determine low percentage of infected patients being treated. The number of patients infected with hepatitis C virus in Poland amounted to 0,5% of country population in 2017. HBV/HCV treatment market makes a significant part of infectious disease market. Ca. 97% of HBV/HCV market products are drugs used in therapies. HBV and HCV treatment market is expected to grow in revenue from USD 17191 mln in 2017 to USD 18736 mln in 2024, at a 5Y growth rate of 1,6%. HBV vaccines market makes 3% of infectious disease market and is expected to grow fast from USD 646 mln in 2018 to USD 2194 mln in 2023, at a 5Y growth rate of 27,7%. HCV vaccine is anxiously expected market product. Major end drugs and vaccines recipients are: hospitals, private laboratories, doctors' surgeries, public health laboratories and blood banks.

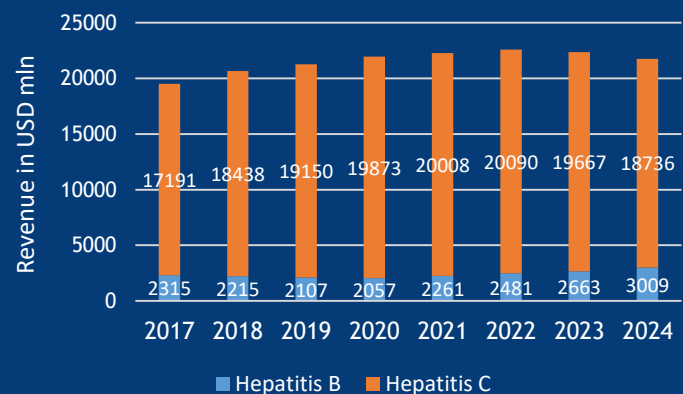
Technology

Proposed vaccine is based on chimeric particles 412-425_sHBsAg built from carrier protein spontaneously formulating virus-like particles (VLP) and the highly conserved epitope 412-425 of the HCV envelope glycoprotein, possessing the ability to induce neutralizing antibody response, capable of binding E2 glycoprotein derived from different genotypes of HCV virus. In addition 412-425_sHBsAg protein is able to elicit the response directed not only against HCV virus but against HBV virus as well, therefore, it could be used as a bivalent vaccine protecting against both HBV and HCV viruses.

Market Analysis and Forecast to 2024

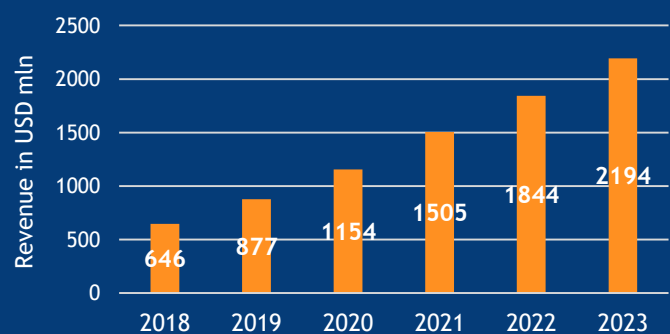


HBV/HVC treatment market
size and forecast for 2017-2024



Source: Global Data, Pharma Intelligence Center, 2017

HBV Vaccines Market
size and forecast for 2018-2023



Source: Global Data, Pharma Intelligence Center, 2017

Technology highlights

- 1 Commercial vaccine against HCV is currently not available because of high HCV virus variability.
- 2 Research confirmed high potential of chimeric virus-like particles 412-425_sHBsAg as vaccine against viral hepatitis C and B types.
- 3 It is crucial to create effective and commercially available vaccine against HCV due to high costs of new generation therapies and constant increase in amount of patients affected.
- 4 New vaccine may have bivalent character and protect against HCV and/or HBV viruses. In addition it could be used in prevention, prophylaxis and/or infection treatment.

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Commercialization opportunities



- ⇒ Licensing relationship
- ⇒ Partnership for further studies and commercialisation
- ⇒ Transfer of ownership

IP Status



The invention was submitted for patenting according to Polish P.410950 and international PCT/PL2016/000002 procedures.

Implementation progress



TRL 4
Technology validated in laboratory conditions

Summary

Vaccine against HCV virus is currently not available on the commercial market. It results from high virus variability what disenables effective vaccine generating. The most common ways of HCV virus infection in high developed countries are: intravenous drug application, transfer virus from mother to child, sexual contacts and cosmetic treatments using needles. In developing countries infections may also be caused by medical procedures. About 80% of HCV virus infections proceed towards chronic phase which may show no symptoms within long period of time. Chronical phase of disease leads in 20% of cases to severe liver damage, liver cirrhosis, and often hepatocellular carcinoma, and a liver transplant does not guarantee healing. Most of potential HCV vaccines have been classified as inactive and withdrawn due to their ineffectiveness. Proposed vaccine could be the subject of commercial sales. Its important asset is unique, bivalent character. It could be offered not only as preventive and prophylactic agent but as treatment for patients infected with both HCV or HBV as well. Currently only few new HBV vaccines obtained advanced stage of development and are prepared to enter the market.

HBV/HCV vaccines as of 2018 Development stage - pipeline drugs

Development Stage	Vaccines #	Vaccines %
Pre-Registration	2	3
Filing rejected/Withdrawn	1	1
Phase III	3	4
Phase II	9	13
Phase I	10	15
Preclinical	31	46
Discovery	11	16

Source: Global Data, Pharma Intelligence Center, 2017

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