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The Russian company Nativa LLC is one the leading manufacturers on the Russian pharmaceutical market. We develop and produce broad range of pharmaceuticals including drugs to treat oncological, multiple sclerosis and asthma diseases.

One of out target activities is the API and finished forms full cycle

production starting from development to manufacturing on the basis of biotechnology synthesis. Biopharmaceutical products of NATIVA are highly technological bioanalogues/biosimilars to treat oncological, chronic autoimmune diseases including the most demanded bioanalogues of the modern class – monoclonal antibodies (MAB).

**Background of JBP (Joint Biosimilar Project)**

Biosimilar market is still attractive for entering by new players. It seems that almost all big international generic pharmaceutical companies probably already have a such strategies, pipelines and even products. If they have not yet begun implementation its own biosimilar project, then it’s could be extremely difficult to convince them.

From another hand, medium-sized local and regional companies are more mobile and flexible. But they don’t have enough resources, needed for independent product developing and fast market enter.

So, such companies should be in our focus. Nativa offer to develop and to pass biosimilar products to their local partners (with the transfer to them of all rights to products in the specified territories), having formed the business alliance with them.

**Initial products for JBP**

Epoetin – fully developed, market authorization in Russia;

Filgrastim – fully developed, market authorization in Russia;

Interferon alfa-2b - fully developed, market authorization in Russia;

PEG- Interferon alfa-2b - fully developed, market authorization in Russia;

Infliximab – developed, phase 1 clinical trials finished, phase 3 on-going;

Darbepoetin - developed, phase 1 clinical trials finished, phase 3 started;

Adalimumab – developed, pre-clinical studies finished;

Trastuzumab – cell line development completed;

Bevacizumab – cell line development completed;

Eculizumab – cell line development completed.

The choice of the South-East region for NATIVA proposal have the following reasons:

a) specifics of the biopharmaceutical market itself characterized by very high clinical and registration costs as well as expensive barriers for technological implementation – all this is affordable either for large multinational corporations or less strong players targeted by NATIVA but in cooperation with other minor companies on the local and neighboring markets;

b) another reason for the choice of the SEA region is somewhat less strict regulation barriers for bioanalogues/biosimilar than on highly regulated markets. This may give the Russian pharma technologies and products more favorable conditions for the fast entrance in cooperation with the local partner.

According to the preliminary investigation of the biopharmaceutical sphere in South East Asia it seems reasonable to propose that JBP in cooperation with NATIVA could be interesting for those companies which plan to expand its biopharmaceutical portfolio or those who wish to enter bio segment by diversifying their oncological and autoimmune portfolio with highly technological bio products. Both types of companies could be interested in distribution and localization for marketing on the local and neighboring countries.

Proposed scheme of cooperation within JBP model between NATIVA (acting as R&D and API source) and the local manufacturing or distribution company is aimed at substantial economy of expenses for entering the biopharmaceutical market thus providing better price competition for own/local biosimilars in comparison with existing brands mostly multinational.

Particularly we are searching for the partners to implement the project of biotechnology transfer from Nativa – the so called JBP (Joint Biosimilar Project). Presentation of the JBP project is attached (“NATIVA\_JBP\_April 18”).

Participation in the JBP project implies that the partner:

a) produces pharmaceuticals on its own or contract manufacturing site;

b) has competencies in tender segment for state needs and other institutional supply including reimbursement system;

c) is interested in acquiring advanced technologies – production of the medicines using gene engineering and monoclonal antibodies;

d) is ready to invest in registration clinical trials and registration in his territory or co-invest in international multi-center trials.

In case of interest to the above mentioned offers we would be ready to discuss any forms of cooperation in the field of pharmaceutical business.

Best regards,

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