
Licensing of novel, safer, DIVA enabled S19 Δ per vaccine candidate for Brucellosis developed by ICAR-IVRI to Hester Biosciences Pvt. Ltd., Ahmedabad

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Biotech Consortium India Limited (BCIL) in partnership with Biotechnology Industry Research Assistance Council (BIRAC) facilitated licensing of a novel, safe, DIVA (differentiating infected from vaccinated animals) enabled S19 Δ per vaccine candidate for Brucellosis. The technology has been developed by Indian Veterinary Research Institute (IVRI), an autonomous institute of Indian Council of Agricultural Research (ICAR) with support of Department of Biotechnology (DBT), Government of India, under the Network Project on Brucellosis. The e-licensing ceremony was graced by dignitaries from DBT, ICAR and Department of Animal Husbandry & Dairying (DAHD), BIRAC and BCIL including **Dr. Renu Swarup, Secretary DBT; Dr. T. Mohapatra, Secretary, DARE & DG-ICAR; Dr. B. P Mishra, Director, IVRI; Dr. Praveen Malik, Commissioner, Animal Husbandry, DAHD; Dr Shirshendu Mukherjee, Head, IP and Specialized Services, Mission Director Program Management Unit, BIRAC and Dr. Purnima Sharma, MD, BCIL.**

Brucellosis is a major zoonotic disease widely distributed in both animals and humans, especially in developing countries and is endemic in the bovine population in India. It is caused by *Brucella abortus*, a gram negative, facultative intracellular bacterium. Brucellosis is a major health challenge which causes infertility, retention of placenta and abortion in last trimester in cattle. Due to Brucellosis, milk output reduces by 30%, during the entire life cycle of animal. The infection of brucellosis can also be transmitted to the farm workers and livestock owners.

Brucellosis results in a median loss of US\$ 3.43 billion (Rs. 2,61,64 crores) per year, with more than 95% of the losses occurring in the cattle and buffalo industry besides having a significant human health impact. To tackle the issue, the Government of India has recently launched **National Animal Disease Control Programme for FMD and Brucellosis** with a financial outlay of Rs. 13,343.00 crore for five years (2019-20 to 2023-24) by vaccinating 100% bovine female calves of 4-8 months of age for brucellosis to prevent loss of Rs. 50,000 crore to the Government exchequer and also to increase the economic output of farmers. This mission mode approach for eradication of the diseases is the biggest step any

country of the world has ever taken either for human or animal vaccination programme to control any disease.

The S19 Δ per technology transferred herein, offers unique advantages as compared to the existing vaccines available in the market i.e. S19 and RB51. The live attenuated smooth Brucella strain S19 is the most commonly used vaccine and has proven effective in controlling Brucellosis in many countries over several decades. This method, although gives the highest level of protection, but at the same time, suffers from drawbacks in terms of safety and efficacy and differentiation of infected versus vaccinated animals (DIVA). The other vaccine employing, mutant strain RB51 although has DIVA capability is considered to have a lower efficacy than the live attenuated S19 and moreover it is resistant to rifampicin, one of the drugs of choice for treating human brucellosis.

The current S19 Δ per vaccine candidate developed by IVRI under the DBT Brucellosis Network Project, has higher safety and potency. It is DIVA enabled, safe vaccine and also expected to have 10-fold reduced dose of immunization. The technology has been successfully validated on Swiss albino mice and pregnant guinea pig for immunogenicity, residual virulence, DIVA capability and safety for pregnant animals.

The vaccine candidate has been licensed non-exclusively to Hester Biosciences Pvt. Ltd., headquartered in Ahmedabad, Gujarat, India. Hester is a leading animal and poultry vaccines manufacturing company with plants situated in Gujarat and Nepal. As per estimates, the vaccine will be available to the market within 2-2.5 years.



Dr. Purnima Sharma, MD, BCIL & her team with Dr. Renu Swarup, Secretary, Department of Biotechnology, Dr. B. P Mishra, Director, IVRI, Dr. T. Mohapatra, Secretary, DARE & DG-ICAR, Dr. Praveen Malik, Animal Husbandry Commissioner, during e-licensing ceremony of the novel, safer, DIVA enabled S19 Δper vaccine candidate for Brucellosis