STABLE BACTERIAL EXTRACTS AS PHARMACEUTICALS

FIELD OF THE INVENTION

[001] The present invention relates to novel stable bacterial extract preparations having substantial increased stability overtime, novel methods of preparation thereof, pharmaceutical formulations based on these novel stabilized bacterial extracts, as well as novel routes of administration and delivery devices for treating and/or preventing acute and chronic immunological disorders resulting from infections and/or inflammation.

BACKGROUND OF THE INVENTION

[002] There is an ever increasing interest in the development of pharmaceutically formulations, either liquid or solid, stable overtime, which can be administered to human subjects for treating infections and inflammations which can be easily adaptable to broader routes of administration, such as oral, intranasal, intratracheal, intrapulmonary, transmucosal, topical, buccal, etc.. as well as to disease conditions and stages (acute stage, exacerbations, etc..) of the patients.

[003] Bacterial infections are often implicated in many respiratory conditions and antibiotic treatments are common. The efficacy of antibiotics in treating such disease conditions and exacerbations has been debated. Their overuse has been associated with increased cost and the potential for increased microbial antibiotic resistance.

[004] Bacterial extract lysate preparations, which contain antigens derived from several strains of bacteria, have been shown to increase resistance to infection by these organisms. The way in which these bacterial extract lysates may exert their effects could be multi-fold and is not yet fully understood. Numerous bacterial extracts have been used as immune stimulants and anti- tumor agents. By way of examples, we can cite *Bacillus Calmette-Guerin* (BCG), Polysaccharide, beta 1,3, glucan, the Maruyama vaccine, and extracts of *Bifidobacterium, L. lactis, L. fermentum, L. acidophilus* and, *S. lactis.* Such extracts are thought to stimulate the immune system in a number of ways. One important way is to stimulate lymphocytes, to grow and to produce cytokines. The ability to induce production of such cytokines has a very powerful effect on the immune system.

[005] In particular, several bacterial extract preparations have been already successfully developed by the Applicant for the treatment and/or the prevention of upper tract respiratory disorders. To this regard, we can cite the drug Broncho-Vaxom® which is a bacterial lysate extract from several pathogens frequently responsible for respiratory tract infections, as described *inter alia* in US Patent No. 9,463,209B2. Broncho-Vaxom® is an immunostimulant administered as a capsule, a sachet or drops via the enteral oral route for the prevention and prophylaxis of respiratory tract infections, recurrent respiratory tract infections, such as acute bronchitis, chronic bronchitis, asthma, chronic obstructive pulmonary disease, and emphysema. It has been shown to