OM-89 (Uro-Vaxom) is a bacterial extract prepared from 18 uropathogenic Escherichia coli strains used for the prevention and treatment of recurrent infections of the urinary tract. The immunomodulating effects of the bacterial extract were investigated in a mouse model. After a single oral administration of OM-89, leukocyte activation was demonstrated ex vivo in blood and liver cells using a chemiluminescence assay. An increase of the production of tumor necrosis factor-alpha (TNF-alpha) in supernatants of peritoneal cells was also observed. After repeated oral administration of OM-89, increased serum immunoglobulin G responses against several E. coli strains were found. Also, adjuvant properties of the extract using ovalbumin as an antigen could be demonstrated. In line with these findings in the mouse system, preliminary in vitro data obtained in the human system showed an increase in TNF-alpha and interleukin-6 production after stimulation of monocyte derived dendritic cells with OM-89. The activation of immune cells is likely to be mediated via Toll like receptors (TLRs); thus, the binding of components of the extract to TLR-4 and marginally to TLR-2 could be shown.