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A review of the development of calcium pterins and (250:1 Mol:Mol) calcium folate for the immunotherapy of certain diseases

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The development of a class of immunotherapeutics the calcium pterins, beginning with Ca Pterin•2Cl (Ca-Pterin) and culminating with calcium pterin 6-carboxylate chelate (CP6CC) for several immunologically related preclinical and clinical indications are reviewed here. A preliminary analysis of their immune mechanisms of action is discussed. The preclinical murine models first tested with CaPterin and dipterinyl calcium pentahydrate (DCP), a dimerized version of CaPterin, were four murine breast tumor models. These four models included: C3H/HeN-MTV+ female mice with spontaneous mammary gland adenocarcinomas; mammary EMT6 allografts implanted in non-immune female Balb/c mice; MDA-MB-231 human breast tumor xenographs in SCID mice and MDA-MB-231 human breast tumor xenographs in athymic nude mice. An analysis of the differing tumor responses in these breast tumor models led to the determination that B-cell antibody based antitumor mechanisms were involved. A transgenic hepatitis B murine model and a diabetes induced obese (DIO) type 2 diabetes murine model were also tested with DCP, giving positive results. Further testing and giving positive results with DCP in an *in vitro* tuberculosis model is also reviewed. The investigator hypothesized from a review of the pterin chemical literature that (250:1 mol:mol) calcium folate (designated Ca250 folate•498Cl or CaFolate) can serve as an FDA cleared immunotherapeutic supplement and generate CaPterin, However, mass spectrometry revealed that instead calcium pterin 6-carxylate chelate (CP6CC) was formed *in situ*. Through an observational study in humans, CP6CC derived in this way demonstrated clinical evidence of therapeutic efficacy against colds/flu, osteoarthritis, several cancer cases, type 2 diabetes and other indications, at relative dosages of 0.007 mg/kg•day, approximately 1,000-50,000 times less than those found efficacious with CaPterin and DCP in the preclinical studies. Clinical trials with CaFolate are currently in progress with osteoarthritis and further trials with the active ingredient CP6CC and CaFolate, are planned for cancer and colds/flu.