

Title: A Phase II Study of IMC-A12 (Anti-IGF-I Receptor Monoclonal Antibody in Children with Relapsed/Refractory Solid Tumors (ADVL0821)

IRB# 2010-041

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Synopsis:

This is a **COG** Phase II study of IMC-sA12 (ImClone Systems), a monoclonal antibody to Insulin-Like Growth Factor Receptor (IGF-IR), in pediatric patients with recurrent/refractory solid tumors. IGF plays a role in cancer progression and growth. The use of antibodies to disrupt IGF-IR signaling has shown anti-tumor activity in a variety of cancers in the laboratory setting, in animal models, and in early-phase adult trials. In this trial, the investigators propose to evaluate the safety and efficacy of IMC-A12 in children and adolescents with relapsed or refractory solid tumors.

The primary objectives of this study are:

- To determine the response rate to IMC-A12 in children and young adults with the following recurrent or refractory malignant solid tumors:
 - Osteosarcoma
 - Ewing Sarcoma/Peripheral PNET
 - Rhabdomyosarcoma
 - Neuroblastoma
 - Wilms Tumor
 - Synovial Sarcoma
 - Hepatoblastoma
 - Adrenocortical Carcinoma
 - Retinoblastoma.
- To further define and describe the toxicities of IMC-A12
- To further characterize the pharmacokinetics of IMC-A12