**Title:** COG ADVL1121: A Phase II Study of the Raf Kinase and Receptor Tyrosine Kinase Inhibitor Sorafenib (IND# 69896) in Children and Young Adults with Relapsed/Refractory Rhabdomyosarcoma, Wilms Tumor, Hepatocellular Carcinoma, and Papillary Thyroid Carcinoma

**Purpose:** The objective response rate of sorafenib in children with refractory or relapsed rhabdomyosarcoma, Wilms tumor, hepatocellular carcinoma (HCC), and papillary thyroid carcinoma (PTC). The secondary objectives are to estimate the time to progression for each stratum in comparison to historical controls, further define acute and long-term toxicities, and further characterize the pharmacokinetics and pharmacodynamics of sorafenib in children.

**Eligibility:** Rhabdomyosarcoma and Wilms Strata patients must be greater than or equal to 24 months and less than or greater than 30 years of age at study enrollment. Hepatocellular Carcinoma patients must be greater than or equal to 24 months and greater than 18 years of age at study enrollment. Papillary Thyroid Carcinoma patients must be greater than or equal to 24 months and greater than or equal to 21 years of age at study enrollment.

**Principal Investigator:** Wiley, Joseph M.

**Phase:** II

**For more information, contact:** Entrup, Stephanie

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**Approved Enrollment Number:** 5

**Current Enrollment:** 0
Title: Randomized Study of Vincristine, Dactinomycin and Cyclophosphamide (VAC) versus VAC Alternating with Vincristine and Irinotecan (VI) for Patients with Intermediate-Risk Rhabdomyosarcoma. (COG ARST0531)

Purpose: To compare the early response rates, failure-free survival (FFS), and survival of patients with intermediate-risk RMS treated with surgery, radiotherapy, and vincristine, dactinomycin and cyclophosphamide (VAC) or VAC alternating with vincristine irinotecan (VI). To compare FFS, local control, and survival and patients with intermediate-risk RMS treated with VAC and early (Week 4) radiotherapy compared to delayed (Week 10) radiotherapy, using IRS-IV for historic comparison.

Eligibility: Patients less than 50 years of age who have been newly diagnosed with embryonal RMS, botryoid or spindle cell variants of embryonal RMS, ectomesenchymoma, or alveolar RMS are eligible for this study. Enrollment on D9902 to confirm local histologic diagnosis with central pathology review is required for all patients.

Principal Investigator: Wiley, Joseph M.

Phase: III

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Approved Enrollment Number: 5

Current Enrollment: 1
Title: A Randomized Phase II Trial of Bevacizumab (Avastin) and Temsirolimus (Torisel) in Combination with Intravenous Vinorelbine and Cyclophosphamide in Patients with Recurrent/Refractory Rhabdomyosarcoma. (COG ARST0921)

Purpose: To find out what effects bevacizumab, given with vinorelbine and cyclophosphamide, has on children and young adults with recurrent or refractory rhabdomyosarcoma. To find out what effects temsirolimus, given with vinorelbine and cyclophosphamide, has on children and young adults with recurrent or refractory rhabdomyosarcoma. To compare the effects of treatment with vinorelbine, cyclophosphamide and bevacizumab against the effects of treatment with vinorelbine, cyclophosphamide and temsirolimus.

Eligibility: Patient must be less than 30 years of age at the time of study enrollment. Patients with first relapse or progression of rhabdomyosarcoma or primary refractory disease are eligible. Patients without measurable or evaluable disease are eligible. Patients must have had a previous histological verification of rhabdomyosarcoma at original diagnosis. Patients must have a Karnofsky or Lansky performance status score of equal to or greater than 50%, corresponding to ECOG categories of 0, 1, or 2. Use Karnofsky for patients greater than 16 years of age and Lansky for patients equal to or less than 16 years of age. Patients must have a life expectancy of equal to or greater than 8 weeks. Patients must have fully recovered from the acute toxic effects of all prior chemotherapy, immunotherapy, or radiotherapy prior to entering this study. Patients must have recovered from any surgical procedure before enrolling on this study.

Principal Investigator: Wiley, Joseph M.

Phase: II

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Approved Enrollment Number: 15

Current Enrollment: 1