A pilot phase 2 study of albumin-bound rapamycin nanoparticles, ABI-009, in patients with metastatic, unresectable, low or intermediate grade neuroendocrine tumors (NETs) of the lung or gastroenteropancreatic system

Robert A. Ramirez, DO, FACP[1], Marc Matrana, MD[1], Suma Satti, MD[1], Ryan P. Griffin, MD[1], Ramcharan Thiagarajan, MD, FACS[2], J. Philip Boudreaux MD, FACS[2], Eugene A. Woltering, MD, FACS[2]

[1]Ochsner Clinic Foundation, New Orleans, LA; [2]Louisiana State University Health Sciences Center, Neuroendocrine Tumor Program, New Orleans, LA

LSU Health NEW ORLEANS School of Medicine

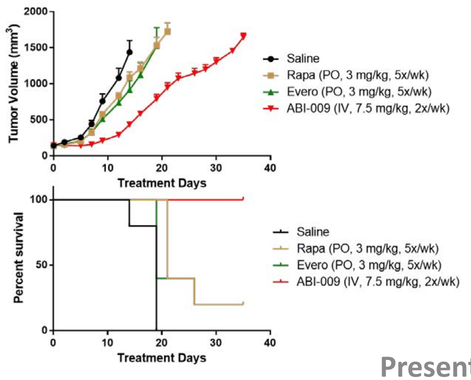
Ochsner Medical Center – Kenner

CLICK TO GO BACK TO KIOSK MENU

Background

- Low and intermediate grade NETs lung or gastroenteropancreatic system are heterogeneous malignancies with limited treatment options beyond surgical resection.
- Studies with the mammalian target of rapamycin (mTOR) inhibitor everolimus (RADIANT 1-4 trials) demonstrated its safety and efficacy; however, progression-free survival is generally less than 12 months.
- Preclinical data demonstrate improved tumor growth inhibition and survival with the mTOR inhibitor albumin bound rapamycin nanoparticles, ABI-009, vs everolimus (dose for dose), indicating that ABI-009 may result in disease control even after everolimus failure.
- The goal of this phase 2 pilot study is to evaluate the utility of ABI-009 in NETs to warrant a full phase 2 clinical study.

Figure 1: ABI-009 Administered IV Compared with Equal Weekly Dosing of Oral Rapamycin and Oral Everolimus (De 2007)



Study Design

- This study is a prospective, single arm, single institution pilot phase 2 study to evaluate the efficacy and safety of ABI-009 in patients with gastroenteropancreatic NETs (GEPNETs) or typical or atypical carcinoid tumors of the lung and prior exposure to everolimus.
- The study will enroll 10 patients with Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.
- The key eligibility criteria is measurable unresectable or metastatic disease with typical or atypical carcinoid tumors of the lung or low or intermediate grade GEPNETs.
- Patients must have progressed or have been intolerant to everolimus.
- Tumor response will be assessed by CT at baseline then every 9 weeks for 1 year, then every 12 weeks thereafter until progression.

Inclusion Criteria

- Unresectable metastatic typical or atypical carcinoid tumors of the lung **OR** low or intermediate grade GEPNETS
- Progressive or intolerant on everolimus

ECOG Performance Status 0-1

ABI-009
administered intravenously at 100 mg/m^2 on days 1 and 8 of a 21-day cycle.

Discontinue for

- Disease progression
- Unacceptable toxicity
- Death

Endpoints

Primary endpoint

- Disease control rate at 6 months measured by RECIST 1.1.

Secondary endpoints

- Safety
- Overall Response Rate

Results

This study is now active and open for enrollment. The anticipated enrollment period is 12 months.

Conclusions

- This pilot phase 2 study may show evidence efficacy of ABI-009 along with safety to warrant a full phase 2 study in patients who have progressed or been intolerant to everolimus treatment.
- ClinicalTrials.gov Identifier: NCT03670030

Presented at the North American Neuroendocrine Tumor Society (NANETS), Seattle, Washington, USA, October 4–6, 2018.

A pilot phase 2 study of albumin-bound rapamycin nanoparticles, ABI-009, in patients with metastatic, unresectable, low or intermediate grade neuroendocrine tumors (NETs) of the lung or gastroenteropancreatic system

Robert A. Ramirez, DO, FACP[1], Marc Matrana, MD[1], Suma Satti, MD[1], Ryan P. Griffin, MD[1], Ramcharan Thiagarajan, MD, FACS[2], J. Philip Boudreaux MD, FACS[2], Eugene A. Woltering, MD, FACS[2]

[1]Ochsner Clinic Foundation, New Orleans, LA; [2]Louisiana State University Health Sciences Center, Neuroendocrine Tumor Program, New Orleans, LA

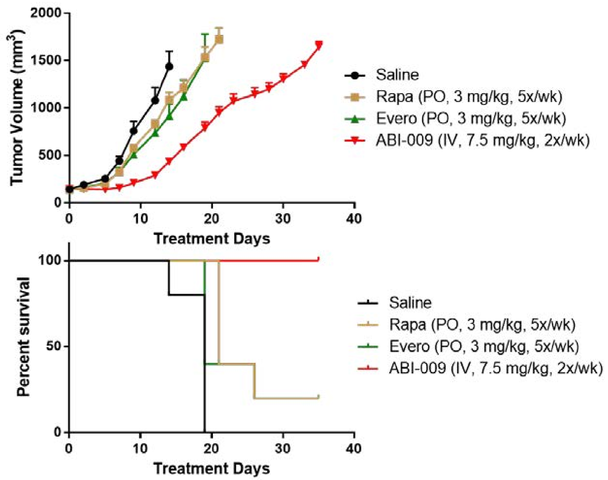
LSU Health NEW ORLEANS School of Medicine

Ochsner Medical Center – Kenner

CLICK TO GO BACK TO KIOSK MENU

Background

- Low and intermediate grade NETs lung or gastroenteropancreatic system are heterogeneous malignancies with limited treatment options beyond surgical resection.
- Studies with the mammalian target of rapamycin (mTOR) inhibitor everolimus (RADIANT 1-4 trials) demonstrated its safety and efficacy; however, progression-free survival is generally less than 12 months.
- Preclinical data demonstrate improved tumor growth inhibition and survival with the mTOR inhibitor albumin bound rapamycin nanoparticles, ABI-009, vs everolimus (dose for dose), indicating that ABI-009 may result in disease control even after everolimus failure.
- The goal of this phase 2 pilot study is to evaluate the utility of ABI-009 in NETs to warrant a full phase 2 clinical study.



Click figure to enlarge.

Figure 1: ABI-009 Administered IV Compared with Equal Weekly Dosing of Oral Rapamycin and Oral Everolimus (De 2007)

Presented at the North American Neuroendocrine Tumor Society (NANETS), Seattle, Washington, USA, October 4–6, 2018.

A pilot phase 2 study of albumin-bound rapamycin nanoparticles, ABI-009, in patients with metastatic, unresectable, low or intermediate grade neuroendocrine tumors (NETs) of the lung or gastroenteropancreatic system

Robert A. Ramirez, DO, FACP[1], Marc Matrana, MD[1], Suma Satti, MD[1], Ryan P. Griffin, MD[1], Ramcharan Thiagarajan, MD, FACS[2], J. Philip Boudreaux MD, FACS[2], Eugene A. Woltering, MD, FACS[2]

[1]Ochsner Clinic Foundation, New Orleans, LA; [2]Louisiana State University Health Sciences Center, Neuroendocrine Tumor Program, New Orleans, LA

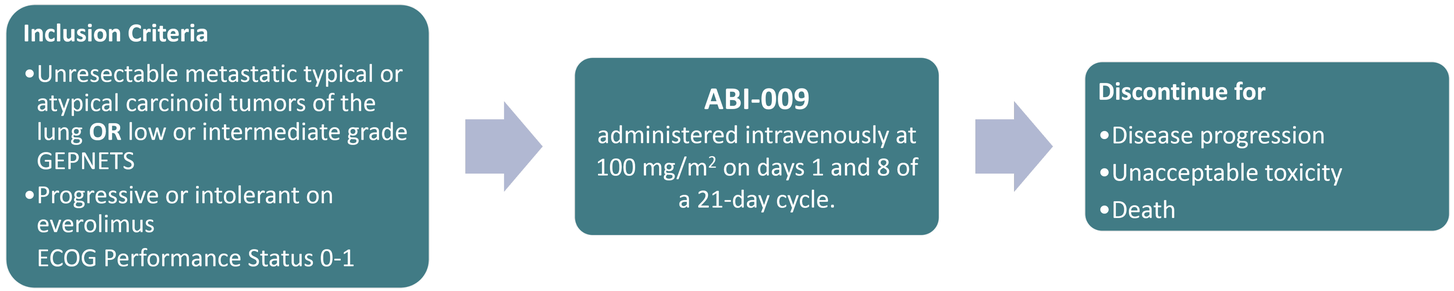
LSU Health NEW ORLEANS School of Medicine

Ochsner Medical Center – Kenner

CLICK TO GO BACK TO KIOSK MENU

Methods

- This study is a prospective, single arm, single institution pilot phase 2 study to evaluate the efficacy and safety of ABI-009 in patients with gastroenteropancreatic NETs (GEPNETs) or typical or atypical carcinoid tumors of the lung and prior exposure to everolimus.
- The study will enroll 10 patients with Eastern Cooperative Oncology Group (ECOG) performance status of 0-1.
- The key eligibility criteria is measurable unresectable or metastatic disease with typical or atypical carcinoid tumors of the lung or low or intermediate grade GEPNETs.
- Patients must have progressed or have been intolerant to everolimus.
- Tumor response will be assessed by CT at baseline then every 9 weeks for 1 year, then every 12 weeks thereafter until progression.



Click figure to enlarge.

Endpoints

Primary endpoint

- Disease control rate at 6 months measured by RECIST 1.1.

Secondary endpoints

- Safety
- Overall Response Rate

Presented at the North American Neuroendocrine Tumor Society (NANETS), Seattle, Washington, USA, October 4–6, 2018.

A pilot phase 2 study of albumin-bound rapamycin nanoparticles, ABI-009, in patients with metastatic, unresectable, low or intermediate grade neuroendocrine tumors (NETs) of the lung or gastroenteropancreatic system

Robert A. Ramirez, DO, FACP[1], Marc Matrana, MD[1], Suma Satti, MD[1], Ryan P. Griffin, MD[1], Ramcharan Thiagarajan, MD, FACS[2], J. Philip Boudreaux MD, FACS[2], Eugene A. Woltering, MD, FACS[2]

[1]Ochsner Clinic Foundation, New Orleans, LA; [2]Louisiana State University Health Sciences Center, Neuroendocrine Tumor Program, New Orleans, LA

CLICK TO GO BACK TO KIOSK MENU

Results

This study is now active and open for enrollment. The anticipated enrollment period is 12 months.

Conclusions

- This pilot phase 2 study may show evidence of promising safety and efficacy of ABI-009 to warrant a full phase 2 study in patients who progressed on or failed everolimus treatment.
- ClinicalTrials.gov Identifier: NCT03670030

References

1. De, T., V. Trieu, Z. Yim, J. Cordia, A. Yang, B. Beals, S. Ci, L. Louie and N. Desai (2007). Nanoparticle albumin-bound (nab) rapamycin as an anticancer agent. Proceedings of the 98th American Association for Cancer Research Annual Meeting (AACR), Los Angeles CA, AACR.

Presented at the North American Neuroendocrine Tumor Society (NANETS), Seattle, Washington, USA, October 4–6, 2018.