NOVOTTF™ THERAPY FOR RECURRENT GLIOBLASTOMA

PRiDe (**P**atient **R**eg**i**stry **D**atas**e**t)

FDA Approved Indication

- NovoTTF-100A System is FDA approved for use as a treatment for adult patients (22 years of age or older) with histologically-confirmed glioblastoma multiforme (GBM), following confirmed disease recurrence after receiving chemotherapy.
- The device is intended to be used as monotherapy as an alternative to standard medical therapy for recurrent GBM after surgical and radiation options have been exhausted.
- Please refer to the Instructions For Use (IFU) for full prescribing information or visit novottftherapy.com

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Methods

- Data from recurrent GBM patients in the United States who started NovoTTF Therapy between October 2011 and November 2013 were captured[1]
- Patients provided consent to use their PHI to advance the understanding of NovoTTF Therapy[1]
- Baseline characteristics were assessed by manual patient chart review
- OS was collected using the Social Security Death Date Registry and obituaries

GBM, glioblastoma; OS, overall survival; PHI, protected health information.

NovoTTF Therapy is approved for the treatment of recurrent glioblastoma. Refer to the IFU for full prescribing information.

1. Wong ET, Engelhard HH, Tran DD, et al. ASCO Proceedings 2014; Publication-Only Abstract # e13033.

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Baseline Demographics

		PRiDe NovoTTF Therapy[1,2] (n=457)
Age (years)	Median (range)	55 (18-86)
Gender	Male	67.6%
	Female	32.4%
KPS	Median (range)	80 (10-100)
	10-60	19.0%
	70-80	46.6%
	90-100	30.9%
	Unknown	3.5%
Recurrence	Median (range)	2 (1-5)
	1st	33.3%
	2nd	26.9%
	3rd-5th	27.4%
	Unknown	12.5%
Prior Treatments	Bevacizumab	>55.1%
	RT + temozolomide	>77.9%
	Debulking surgery	>63.9%
	Carmustine wafers	>3.7%

KPS, Karnofsky performance status; RT, radiotherapy.

1. Wong ET, Engelhard HH, Tran DD, et al. ASCO Proceedings 2014; Publication-Only Abstract # e13033.
2. Novocure data on file.

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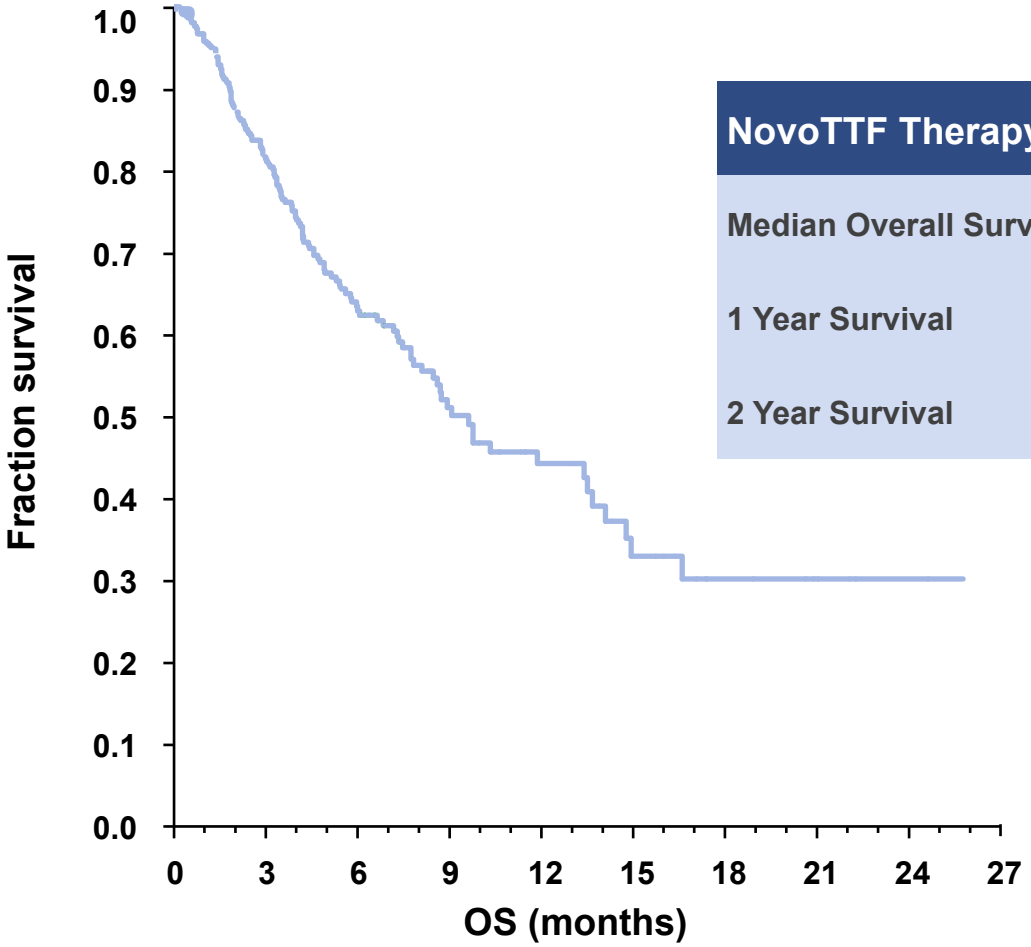
Survival Outcomes



NovoTTF Therapy[1]	N = 457
Median Overall Survival	9.6 mos
1 Year Survival	44%
2 Year Survival	30%

OS, overall survival.

1. Wong ET, Engelhard HH, Tran DD, et al. ASCO Proceedings 2014; Publication-Only Abstract # e13033

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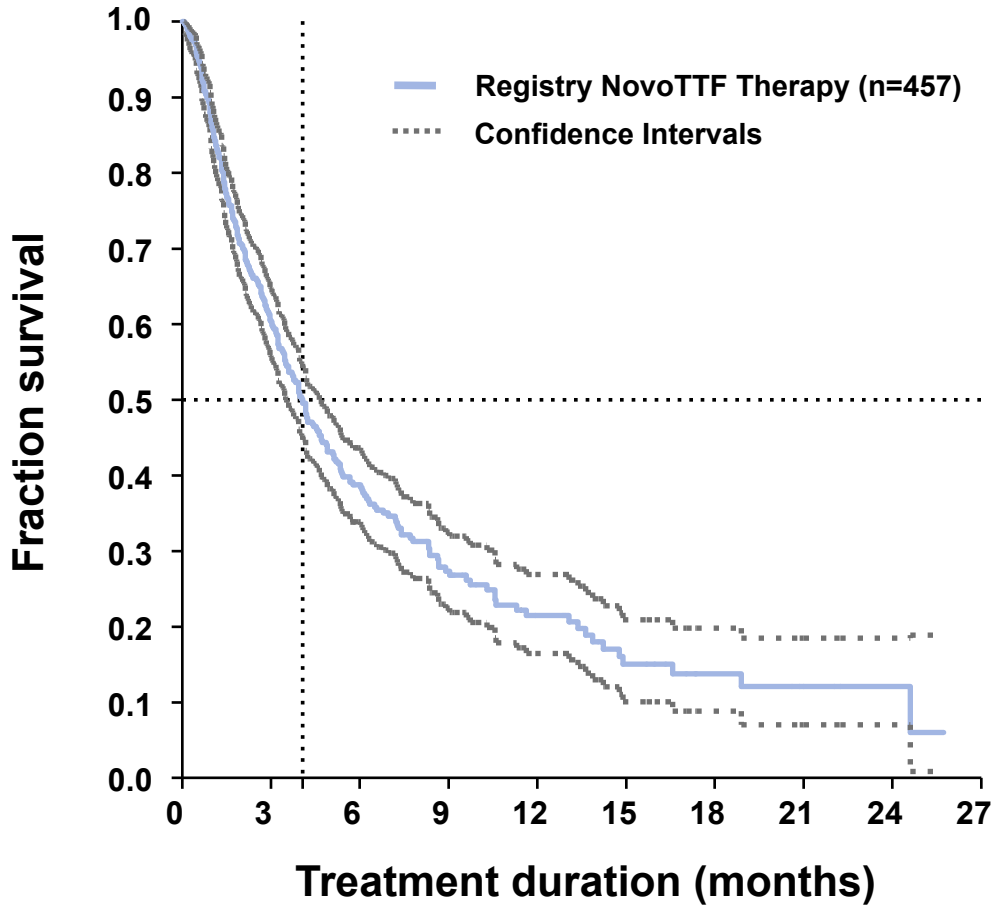
Treatment Duration[1,2]

Median treatment duration = 4.1 months (95% CI, 3.5 to 4.8)



CI, confidence interval.

1. Wong ET, Engelhard HH, Tran DD, et al. ASCO Proceedings 2014; Publication-Only Abstract # e13033
2. Novocure data on file.

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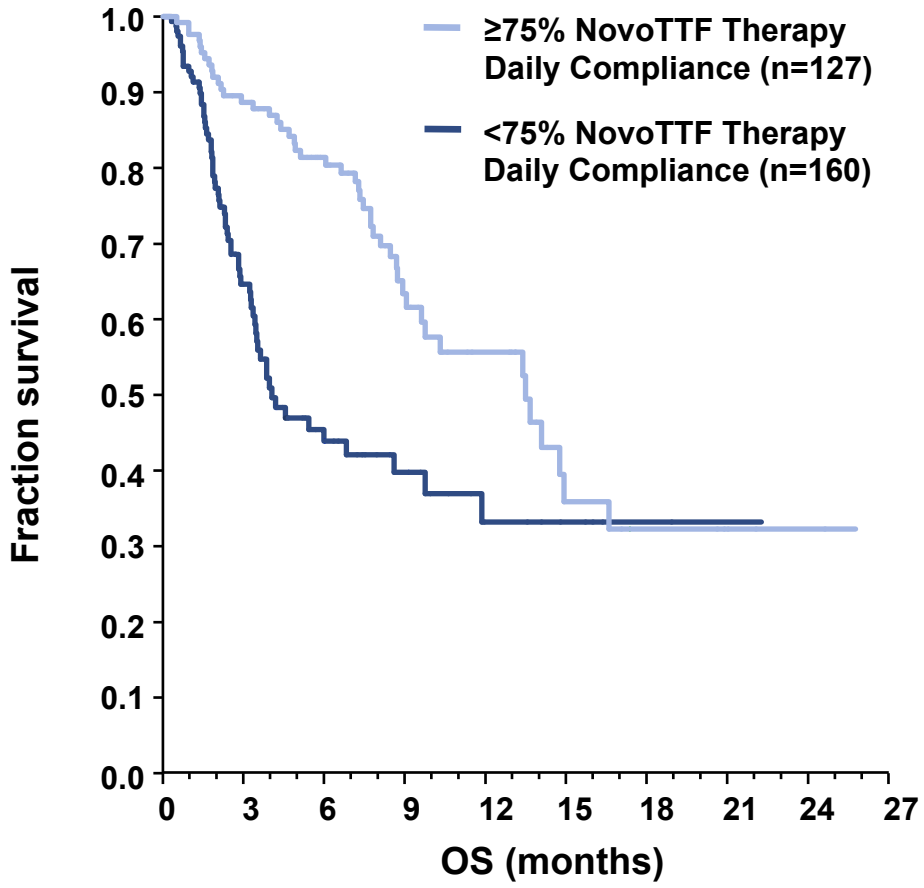
Overall Survival by Compliance[1]

Compliance data available for 287 of 457 registry patients



Median OS	Months
≥75% compliance	13.5
<75% compliance	4.0

Log-rank (Mantel-Cox) Test	
Chi square	18.44
df	1
P value	<.0001

≥75% vs <75% Daily Compliance	
HR	0.43
95% CI of ratio	0.29 to 0.63

CI, confidence interval; df, degrees of freedom; HR, hazard ratio; OS, overall survival.

1. Novocure data on file.

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PRiDe: Overall Survival by Prognostic Factors

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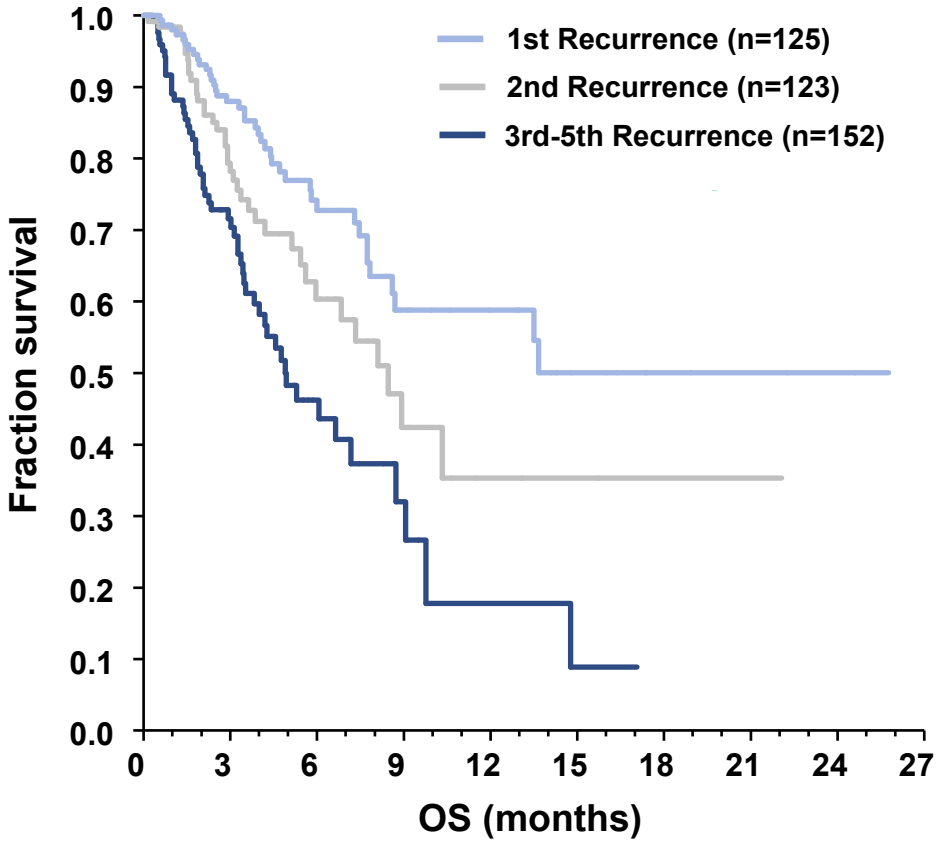
Overall Survival by Number of Recurrence[1]



Median OS	Months
1st recurrence	20.0
2nd recurrence	8.5
3rd-5th recurrence	4.9

Log-rank (Mantel-Cox) Test	
Chi square	24.88
df	2
P value	<0.0001

1st vs 2nd Recurrence	
HR	0.6
95% CI	0.4-0.9
P value	0.0271

1st vs 3rd-5th Recurrence	
HR	0.3
95% CI	0.2-0.5
P value	<0.0001

OS, overall survival.

1. Wong ET et al. In Proceedings from the 16th Biennial Canadian Neuro-Oncology Meeting; June 12-14, 2014; Halifax, Nova Scotia. Clinical Science Oral Abstract Presentation C7.

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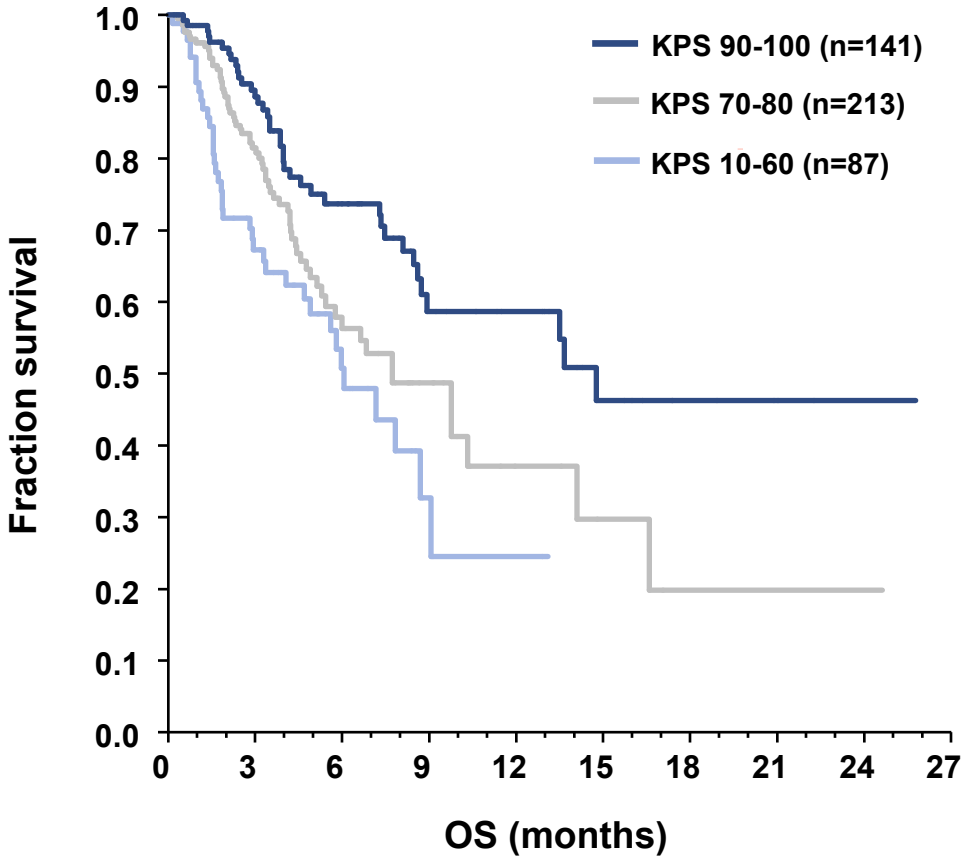
Overall Survival by KPS[1]



Median OS	Months
KPS 90-100	14.8
KPS 70-80	7.7
KPS 10-60	6.1

Log-rank (Mantel-Cox) Test	
Chi square	16.12
df	2
P value	0.0003

KPS 90-100 vs 70-80	
HR	0.6
95% CI	0.4-0.9
P value	0.0070

KPS 90-100 vs 10-60	
HR	0.4
95% CI	0.2-0.6
P value	<0.0001

CI, confidence interval; df, degrees of freedom; KPS, Karnofsky performance status; OS, overall survival.

1. Wong ET et al. In Proceedings from the 16th Biennial Canadian Neuro-Oncology Meeting; June 12-14, 2014; Halifax, Nova Scotia. Clinical Science Oral Abstract Presentation C7.

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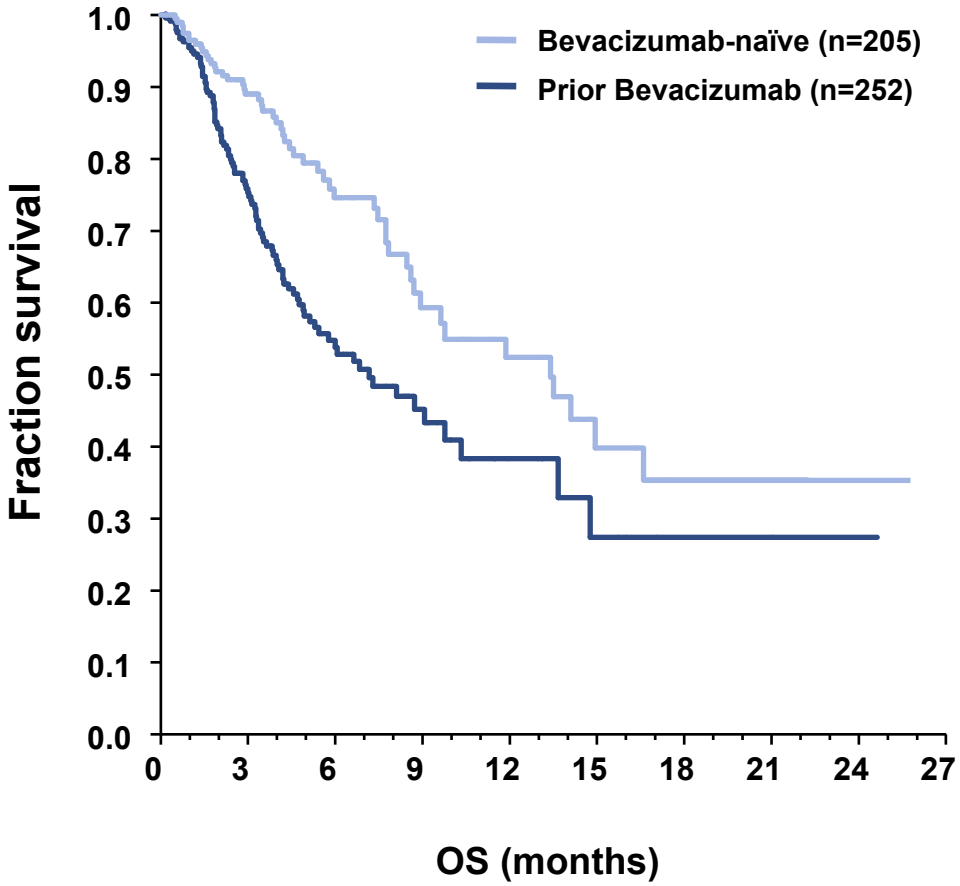
Overall Survival by Prior Bevacizumab Treatment[1]



Median OS	Months
Bevacizumab-naïve	13.4
Prior bevacizumab	7.2

Log-rank (Mantel-Cox) Test	
Chi square	14.54
df	1
P value	0.0001

Bevacizumab-naïve vs Prior Bevacizumab	
HR	0.54
95% CI	0.39-0.74

CI, confidence interval; df, degrees of freedom; HR, hazard ratio; OS, overall survival.

1. Wong ET et al. In Proceedings from the 16th Biennial Canadian Neuro-Oncology Meeting; June 12-14, 2014; Halifax, Nova Scotia. Clinical Science Oral Abstract Presentation C7.

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Safety Analysis[1]

Adverse Event	Percentage of Patients (n=457)
Skin reaction	24.3
Heat sensation	11.3
Neurological disorder	10.4
Seizure	8.9
Electric sensation	7.7
Headache	5.7
Pain/discomfort	4.7
Fall	3.9
Psychiatric disorder	2.9
Gastrointestinal disorder	2.9
Fatigue	2.5
Vascular disorder	1.6
Weakness	1.4
Infections	1.4
Eye disorder	1.3

1. Novocure data on file.

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Conclusions

- The PRiDe dataset represents 457 patients treated in the United States between October 2011 and November 2013[1]
  - Novocure believes this represents about 5% of the treated recurrent GBM population in the United States[2]
- OS with NovoTTF Therapy is significantly longer in the real-world setting than that observed in the EF-11 pivotal trial[3,4]
  - Median OS: 9.6 vs 6.6 months
  - 1-Year survival: 44% vs 20%
  - 2-Year survival: 30% vs 9%
- Compliance is a clear predictor of survival on NovoTTF Therapy[3,4]
  - PRiDe dataset confirms that at least 18 hours of treatment per day with NovoTTF Therapy achieves longer survival outcomes
- The PRiDe dataset confirms that certain prognostic factors are predictive for survival[5]
  - Bevacizumab-naïve patients
  - Performance status
  - Use in 1st recurrence
- No new safety signals have been detected in the real-world setting[3]
- Skin irritation was the only common device-related adverse event, which is consistent with the results from the EF-11 pivotal trial[3,4]

GBM, glioblastoma; OS, overall survival.

1. Wong ET, Engelhard HH, Tran DD, et al. ASCO Proceedings 2014; Publication-Only Abstract # e13033. **2.** Ostrom QT, Gittleman H, Farah P, et al. *Neuro Oncol*. 2013;15(suppl 2):ii1-ii56. **3.** Novocure data on file. **4.** Stupp R, Wong ET, Kanner AA, et al. *Eur J Cancer*. 2012;48(14): 2192-2202.**5**. Wong ET et al. In Proceedings from the 16th Biennial Canadian Neuro-Oncology Meeting; June 12-14, 2014; Halifax, Nova Scotia. Clinical Science Oral Abstract Presentation C7.

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