## TAKE THE PATH TO AVOID TREAT MENT DELAYS



## GLIADEL® WAFER WORKS AT DAY 1

- You don't have to wait 14 days: Traditional treatment for high-grade malignant gliomas begins 14 days after a tumor is removed
- Cells may double after 10 days: After resection, residual tumor cells may double in number approximately every 10 days¹
- Only 1 therapy: There is only 1 drug approved for high-grade malignant gliomas that avoids treatment delays post surgery
- Significantly increases median survival after initial craniotomy in patients with high-grade malignant glioma (from 11.6 to 13.9 months)<sup>2</sup>

REFERENCES: 1. Matsutani M. Cell kinetics. In: Berger MS, Wilson CB, eds. The Gliomas. 1st ed. Philadelphia, Pa: WB Saunders Co; 1999;204-209. 2. GUADEL\* Wafer Prescribing Information.

Patients undergoing craniotomy and implantation of GLIADEL® Wafer for malignant glioma should be monitored closely for complications of craniotomy. During a randomized trial of GLIADEL® Wafer vs placebo implanted during initial resection, four categories of adverse events occurred that were possibly treatment-related: seizure (33.3% vs 37.5%); brain edema (22.5% vs 19.2%); healing abnormalities (15.8% vs 11.7%) including cerebrospinal fluid (CSF) leaks (5.0% vs 0.8%); and intracranial infection (5.0% vs 6.0%).

Cases of intracerebral mass effect unresponsive to corticosteroids have been described in patients treated with GLIADEL® Wafer, including one case leading to brain herniation. GLIADEL® Wafer contains carmustine and should not be given to patients who are allergic to carmustine. There are no studies assessing the reproductive toxicity of GLIADEL® Wafer. Carmustine can also cause fetal harm when administered to a pregnant woman.

GLIADEL® WAFER (polifeprosan 20 with carmustine implant)

pomoprosan zo wim carmosino impiani

THE PATH TO EXTEND LIVING

## GLIADEL® WAFER (polifeprosan 20 with carmustine implant) Ry only

5

There are no studies of GLADEL® Water in pregnant women. If GLADEL® Mater is used during pregnancy, or if the patient becomes pregnant after GLADEL® Water implemation, the patient becomes pregnant after GLADEL® Water implemation, the patient	Happings Time are no sides associate the production body of MURE! White Commands as water composered of MURE! White, care may also fill them when interested to a prepare woman. Lamender to also also down to be anything to a manager in rise at the design of the 1.7 to, and any design women and to produce only it may be a manager to the terminated to the commands of	MAUNIBEES UN CHRISTON FOR MAINN AIR PROFIT AND TRADERING OF SUBJECT VIBER STAND FOR THE STAND STAND STAND AND THE STAND	CONTRANDICATIONS GLADEL Video constants communities, GLADEL® Water aboutd not be objen to inclividuals who have demonstrated a previous hyperson-body to communities or any of the components of GLADEL® Water.	NITICATIONS AND USAGE  AUDICE Visible is indicated in newly-diagnosed high-grade malignant glients patients as an adjunct to surgery and radiation.  GLUCE: Visible is indicated in meaninnt gliobissions malignant putients as an adjunct to surgery, and radiation.	BILL OWNERS
---	--	---	---	---	-------------

PRILATIPAM.

I production to the control of production of the verticals regard double be needed to present it where the control of a control of production of the control of a control of the control of

Body System GLIGGE: Warier N=120 Pfacebe N=120 at (%)	COMMON ADVERSE EVENTS DISSERVED IN 25% OF PATIENTS RECEIVING GLADRE" WAVER AT INITIAL SURGERY	Planting Statery The following data are the most frequently occurring adverse events observed in 5% or more of the newly-diagnose malignam distrat patients during the trial.
		f the newly-diagnosed

Second Color   Seco	bris	Hyposthesia Paresthesia Paresthesia Thirlog abnormal Abnormal gatt Dizziness Gazin mai convulsion	hy disorder ralysis by		Nervous system Lampidgle Lampidgle Lampidgle Confusion Donfusion Pain adenu 2	Musedoskeletzi system Myzsthonia	Metabelic and notritional disorders Healing abnormal Peripheral edema 1	Endorches system Diabetes mellitus Cushings syndrome 4	Digesthe system Haussa Haussa Vomittig Constitution Constitution Diarmos Diarmos Liver Nunction (tests abnormal 1	Cardiovascodar system Dep thrombophiebits One phonoary emboliss Hemorrhage	Accidental injury Chest pain Allergic reaction	Pain 1 Abdominal pain 1 Back pain 1 Face eterns	5 %	body as a whole Approvation reaction* Sometimes Headache Comments Sometimes	Sody System GLGSSE:*	PATIENTS RECEIVING GLADI
	an money	<u> </u>	<u> </u>	<u> </u>	-8888	5(4) 6(5)		99	14 1 1 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	172 (10) 10(8) 10(8) 8(7) 7(8)	D 000	29.2 <u>6</u> g	222	23.68	GLIGORE • Water N=120 Placebe N=120 n (%)	INTIAL S

Urisary incontinence "Adverse events coded to the COSTART term "aggre or general deterioration of candition (e.g. condition)	Diplopia Urageallal system Urbary tract infection	Abnormal wision Visual field defect Eye disarder	Alopetial Special senses Continuentical notions	Sidn and approvide Cast Right	Respiratory system Program Program
9 (8) svetion reaction" were usuall heseth/Karnofsky/neurologic	10(8)	ଧର √। ଭଲକୁ	8 TO 100	1102	10(8)
9 (8) satisfar vario usually events involving tomor/biosecs progression terrolsy/neurological/physical deterioration).	13 (11)	00 7 (67)	a 14 (ii)	13 [1]	<b>3</b> 8

COMMON ADVERSE EVENTS OBSERVED IN 24% OF PATIENTS RECEIVING GLIADEL* WAFER AT SURGERY FOR RECURRENT DISEASE	Singerful Mentamenthisses.  Singerful Mentamenthisses.  The Sharing bedgerfather activate earth year observed in 4% or note of the patients providing GLUDES "Within at the Sharing bedgerful point for mental agreem offices, waver given in a populating that he placed water out to have been recognished only event and count promote many common in the CLUDES, "White' group are black in these devices exerts were state and promote moderable for events of the development of the Sharing protein way to 17 months.	Uray-mild system         10 (8)         15 (11)           Uray-mild relation         10 (8)         15 (11)           Uray-moderates         9 (8)         9 (8)           "Access exercis codes to SCRIFTER* "Approxison exercises are exercise industry to confidence programming and provided descriptions."         or present descriptions on careful to pay or confidence programming and provided descriptions.
---	--	--

RECEIVING GLADEL*	NG GLIADEL* WAFER AT SURGERY FOR H	ECURRENT DISEASE
Body System Adverse event	GLIADEL* Water Water With Carmeraine [Na-110] n (%)	PLACEBO Weder Without Carmestins [N=112] n (%)
Body as a Whole Faver Pain*	35 93	3(8)
Digestive System Newsea and Verniting	8 (8)	7 (6)
Metabolic and Hubrillonal Disorders Healing Abnormal*	15 (14)	6 (S)
Nervous System  Convision Hemiologia Hemiologia Heacitale Sommelenze Contralenze Contralenze Sommelenze Sommelenze Sommelenze Hemiologia Hemiologia Hemiologia Hemiologia Hemiologia Hemiologia Hemiologia Hemiologia Hemiologia	44767822 2006233333	<del>239<u>5959</u> 4-46858</del>
Sidn and Appendages	68)	4 (4)
Urogenital System Urinary Tract Infection	23 (21)	19(17)

THE SECTION OF THE PROPERTY OF

Continuation (Space Topolitation (PK) potention (TN)

Depth Space Space Topolitation (PK)

Depth Space Space

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. U.S. Patont Nos. 4,789,724 and 4,757,128.

Rev. 11/2005