

## Imvax Corporate Overview

A clinical-stage biotechnology company with a unique platform for personalized, whole tumorderived immunotherapies

March 2023

### A compelling immuno-oncology platform opportunity

- The Imvax Goldspire<sup>™</sup> platform harnesses decades of research and multiple validated technologies to create a pipeline of personalized, whole tumor-derived treatments targeting intractable solid tumors
- Lead asset to treat newly-diagnosed GBM currently in Phase 2b
- Additional IND planned for endometrial cancer in 2023
- Established GMP manufacturing capabilities at Imvax
- Projected up to \$6B annual revenue in addressable markets, largely underserved therapeutic areas (on a non-risk adjusted basis)
  - \$2B \$3B global peak sales in ndGBM alone
- Seasoned leadership with deep biopharma development and commercialization experience





#### Team that's been directly involved in development, approval and commercialization of multiple biological modalities



#### John Furey CEO

- COO, Spark Tx
- SVP Global Operations, Baxalta
- VP Baxter & Pfizer



#### **David Andrews CMO**, Founder

- Chief. Tumor Division, Dept of Neurosurgery, TJU
- Trained at NY Presbyterian & Memorial Sloan Kettering



#### Mark Exley CSO

- VP, AgenTus (now MiNK)
- Co-Founder, NKT Tx
- Harvard & Manchester Faculty
- Current Honorary Academics



**Tyler Curiel** 

of Medicine

**Scientific Advisor** 

Prof of Med, Microbiology

and Immunology at the

Dartmouth Geisel School

- CFO, Mesoblast
- SVP, Bus Dev, ContraFect
- +15 yrs investment banking



#### **Sean Hemingway COO**

- SVP. Global Head of BioLife Plasma Services, Takeda
- SVP, Takeda Manufacturing



#### John Limongelli CLO

- SVP, GC and CS, Neos Therapeutics
- SVP. GC. Trevena



Management Non-Management

#### Shefali Agarwal **Scientific Advisor**

- Pres & CEO, Onxeo
- Prev. EVP, CMDO Epizyme







- Head of HR • HR Director, Aramark
- Head of HR. Biocoat

#### **Josh Muntner** CFO

### Imvax pipeline: Focused on solid tumor types

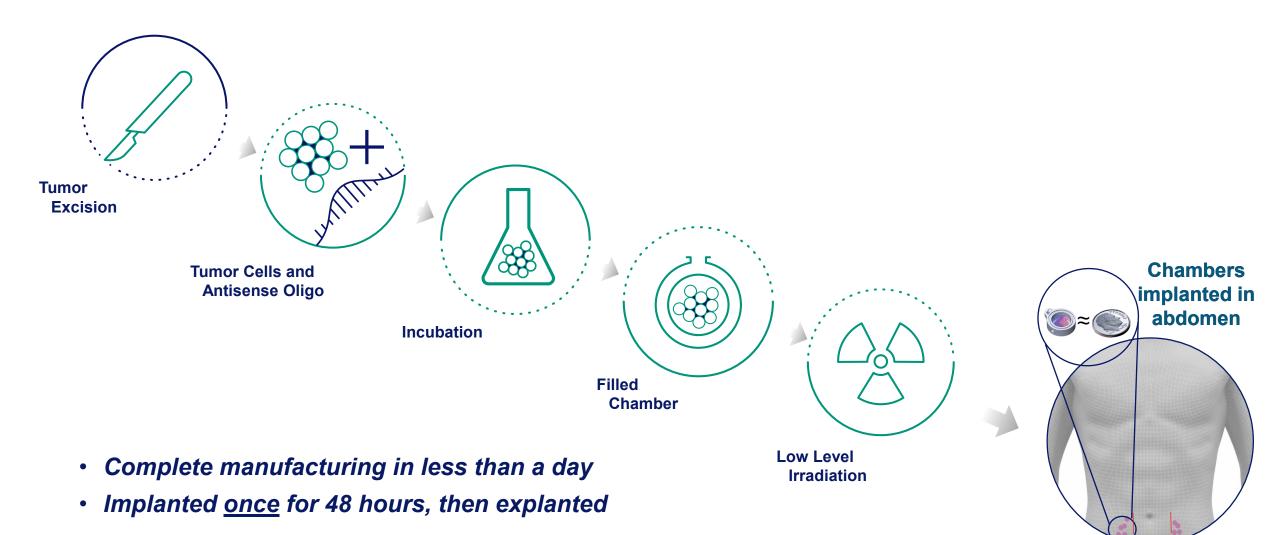
		Target Validation	IND-enabling	Phase 1	Phase 2	Phase 3
Glioblastoma	IGV-001					Phase 2b underway
Endometrial Cancer	IEC-001			IND filing	g in 2023	
Hepatocellular Carcinoma	IHC-001					
Urothelial Carcinoma	IUC-001					
Ovarian Cancer	IOC-001					



### Imvax's Goldspire Platform

A Powerful Approach to the Complexity of Solid Tumors

### Imvax's Goldspire process





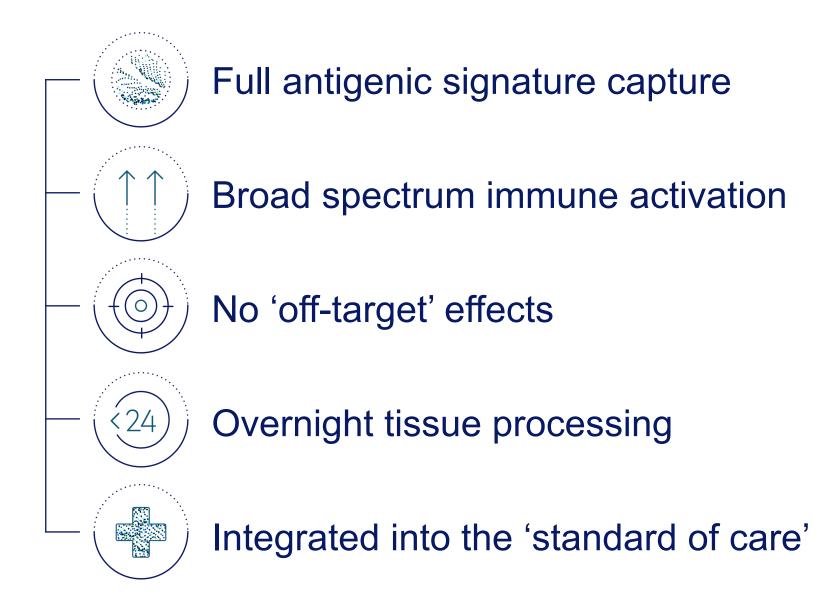
#### **Goldspire fits seamlessly into GBM standard of care**

#### Tumor **Inpatient Recovery Patient Discharge Outpatient Treatment** Excision Chemotherapy Standard of Care Radiotherapy DAY 0 DAY 1 – 3 **DAY 42** DAY 4 Tumor **Imvax Proprietary Process Patient Discharge Outpatient Treatment** Excision Standard Chamber Inpatient Chamber **Cell Processing** of Care + Implant Recovery Explant Chemotherapy Imvax 8 Treatment Radiotherapy

#### **Entering Phase 2 for Newly-Diagnosed GBM**

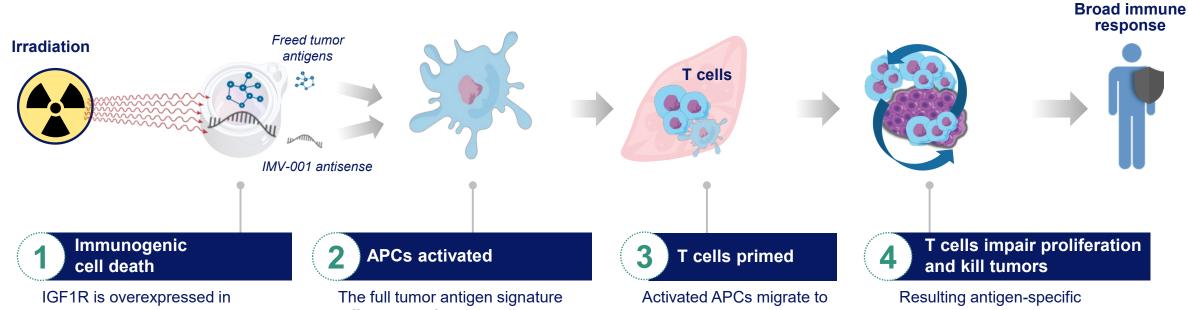


### **Goldspire platform has multiple advantages**





### Immune response effectively attacks tumors on multiple fronts



malignant cells, where it promotes cell survival and tumor progression. The use of IMV-001 (antisense oligonucleotide against IGF1R), radiation and implantation within small specialized chambers induces immunogenic cell death during the short implantation in the body. The full tumor antigen signature diffuses out of the chamber's micropores and is picked up by local 'antigen presenting

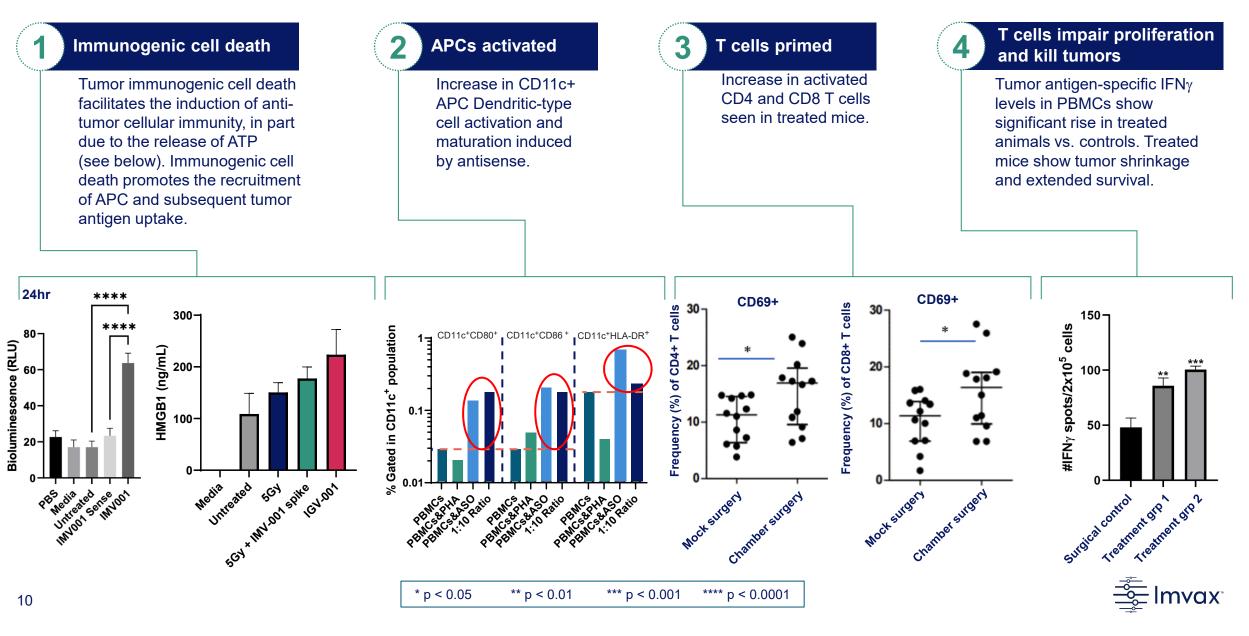
cells' (APC).

Free IMV-001 also diffuses out of the chambers and serves as a second layer of immune stimulation for local APCs. Activated APCs migrate to local draining lymph nodes, where they prime T cells against the tumor antigens. Implanting the chambers remote from immunosuppressed tumor-draining lymph nodes elicits an optimal immune response

T cells migrate to tumor site and provide anti-tumor cytotoxicity. These T cells also produce IFN $\gamma$ , which inhibits tumor cell proliferation and activates other immune cells.



### Preclinical data support multi-component mechanism of action



## Lead Program: GBM

### **GBM Program Overview**

- Glioblastoma multiforme (GBM) is the most common malignant tumor of the brain and CNS
- Newly-diagnosed GBM patients have median overall survival (OS) or life expectancy of approximately 16 months, and less than 7% of GBM patients survive to five years after diagnosis
  - Standard of care treatment is surgery followed by radiotherapy and chemotherapy
- Strong patent position exclusively licensed from Thomas Jefferson University
- Orphan Drug Designation granted by FDA; less than 14,000 newly diagnosed patients in the US annually
  - Underserved market with no recent innovation
- Imvax's GBM program seeks to build on groundbreaking Phase 1b data



### Phase 2b clinical trial underway

- Randomized, multicenter, double-blind, placebo-controlled, Phase 2b study to assess IGV-001 in newly diagnosed patients with glioblastoma post-craniotomy
- Compares efficacy of a one-time treatment with IGV-001 plus standard-of-care (SOC) GBM therapy (RT + TMZ) with SOC GBM therapy alone
- Study population limited to Stupp-eligible patients
  - Excludes patients > 70 yrs old, with extensive intracranial disease in both hemispheres or multi-centric disease
- 93 patients will be randomized 2:1 (IGV-001 + SOC vs SOC)
- Conducted at up to 25 US sites
- Primary efficacy endpoint: progression free survival (PFS)
- Overall survival (OS) is the key secondary efficacy endpoint
- Potential PFS data in 2Q 2025 and then OS follow-up in 2Q/3Q 2026



### Phase 1b results published in peer-reviewed *Clinical Cancer Research* in April 2021

- Ph1b trial of IGV-001 in patients with newly diagnosed glioblastoma
- Primary and secondary objectives were safety and tumor progression
- Broad inclusion criteria resulted in enrollment of difficult to treat patients
- 33 patients randomized to receive varying number of chambers and/or differing lengths of exposure

Number of chambers and length of implantation				
	24 hours 48 hour			
10 chambers	N = 6	N = 5		
20 chambers	N = 5	N = 17*		

CLINICAL CANCER RESEARCH | CLINICAL TRIALS: IMMUNOTHERAPY

#### Phase Ib Clinical Trial of IGV-001 for Patients with Newly Diagnosed Glioblastoma 🔤



David W. Andrews<sup>1,2</sup>, Kevin D. Judy<sup>1</sup>, Charles B. Scott<sup>3</sup>, Samantha Garcia<sup>4</sup>, Larry A. Harshyne<sup>1</sup>, Lawrence Kenyon<sup>5</sup>, Kiran Talekar<sup>6</sup>, Adam Flanders<sup>6</sup>, Kofi-Buaku Atsina<sup>6</sup>, Lyndon Kim<sup>7</sup>, Nina Martinez<sup>8</sup>, Wenyin Shi<sup>9</sup>, Maria Werner-Wasik<sup>9</sup>, Haisong Liu<sup>9</sup>, Mikhail Prosniak<sup>4</sup>, Mark Curtis<sup>5</sup>, Rhonda Kean<sup>4</sup>, Donald Y. Ye<sup>1</sup>, Emily Bongiorno<sup>4</sup>, Sami Sauma<sup>10</sup>, Mark A. Exley<sup>2</sup>, Kara Pigott<sup>2</sup>, and D. Craig Hooper<sup>1,4</sup>

#### ABSTRACT

**Purpose:** Despite standard of care (SOC) established by Stupp, glioblastoma remains a uniformly poor prognosis. We evaluated IGV-001, which combines autologous glioblastoma tumor cells and an antisense oligonucleotide against IGF type 1 receptor (IMV-001), in newly diagnosed glioblastoma.

Patients and Methods: This open-label protocol was approved by the Institutional Review Board at Thomas Jefferson University. Tumor cells collected during resection were treated *ex vivo* with IMV-001, encapsulated in biodiffusion chambers with additional IMV-001, irradiated, then implanted in abdominal acceptor sites. Patients were randomized to four exposure levels, and SOC was initiated 4–6 weeks later. On the basis of clinical improvements, randomization was halted after patient 23, and subsequent patients received only the highest exposure. Safety and tumor progression were primary and secondary objectives, respectively. Time-to-event outcomes were compared with the SOC arms of published studies.

https://clincancerres.aacrjournals.org/content/27/7/1912

**Results:** Thirty-three patients were enrolled, and median followup was 3.1 years. Six patients had adverse events (grade  $\leq$ 3) possibly related to IGV-001. Median progression-free survival (PFS) was 9.8 months in the intent-to-treat population (vs. SOC, 6.5 months; P = 0.0003). In IGV-001–treated patients who met Stupp-eligible criteria, PFS was 11.6 months overall (n = 22; P = 0.001) and 17.1 months at the highest exposure (n = 10; P = 0.0025). The greatest overall survival was observed in Stupp-eligible patients receiving the highest exposure (median, 38.2 months; P = 0.044). Stupp-eligible patients with methylated O<sup>6</sup>-methylguanine–DNA methyltransferase promoter (n = 10) demonstrated median PFS of 38.4 months (P = 0.0008). Evidence of immune activation was noted.

Conclusions: IGV-001 was well tolerated, PFS compared favorably with SOC, and evidence suggested an immune-mediated mechanism (ClinicalTrials.gov: NCT02507583).

\* 15 patients if two patients with bihemispheric/multicentric disease excluded



### Ph1b study met safety endpoints

Efficacy data compelling across broad spectrum of patients

Patients with Newly Diagnosed Glioblastoma					
	Standard of Care <sup>1</sup>				
Groups	Total ITT	Highest Dose Cohort ITT	Stupp-Eligible <sup>2</sup> Highest Dose Cohort		
Patients (n)	(n=33)	(n=15)	(n=10)	(n=1,059)	
mOS	17.3 months	25.3 months	38.2** months	16.2 months	
OS24†	39%	50%	60%	30%	
PFS6	86%	85%	90%	56%	
mPFS	9.8* months	17.3** months	17.1** months	6.5 months	

• No concerns regarding safety profile of product; AEs largely procedural related and addressed during the trial

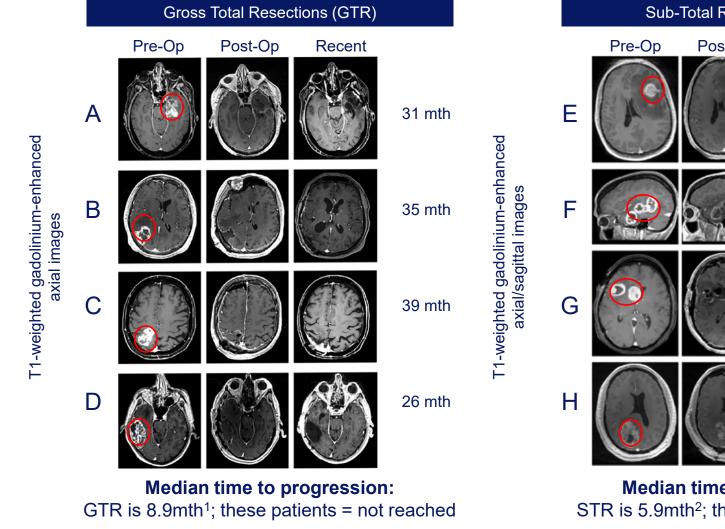
• Statistically significant PFS and survival benefits compared to SOC seen particularly at higher exposures ITT and when the Stupp Inclusion/Exclusion criteria are applied and even more significant in the MGMT+ subgroup of patients

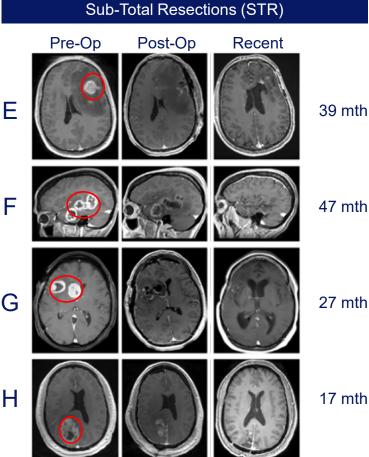
Note: figures based on May 1, 2020 data cut-off.

15 1 SOC data only available for age cut < vs.> 60 in Stupp; Stupp et. al. Lancet Oncology 10: 459-466 (2009) 2 Stupp-Eligible excludes >70 yrs old and extensive intracranial disease in both hemispheres or multi-centric disease



# Radiographic responses in Phase 1b study show meaningful delay to disease progression





**Median time to progression:** STR is 5.9mth<sup>2</sup>; these patients = 32.7mth



<sup>1</sup> Chaichana KL et. al. (2014) World Neurosurgery 82: 257-265 <sup>2</sup> Fukui A et. al. (2017) World Neurosurgery 98: 73-80

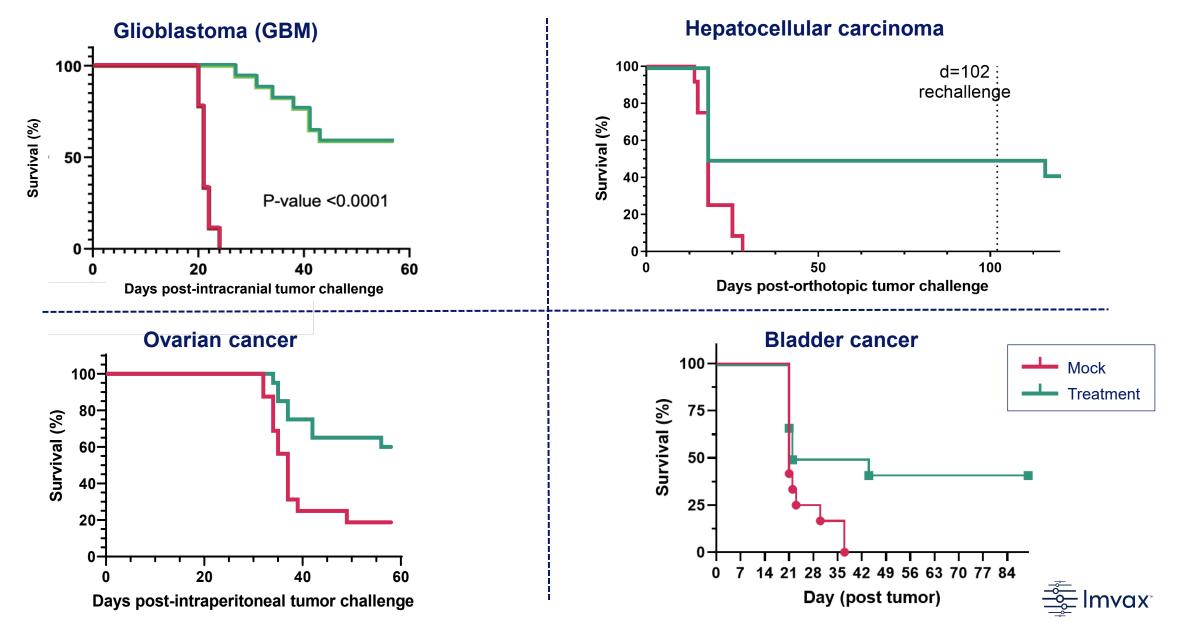
## Pipeline in Solid Tumors

### Preclinical data supports potential in broad range of solid tumors

Tumor	Model Status		
GBM	Compelling mono-activity, additional combo. activity		
Ovarian	Compelling durable mono-activity		
HCC	Compelling durable mono-activity, rechallenge data		
Bladder	Compelling durable mono-activity		
PDAC	Modest statistical benefit to date		
CRC	Modest statistical benefit to date		



#### In vivo data demonstrating extended survival in multiple animal models



# Preclinical data provides MOA support and shows promise in multiple solid tumors

- Powerful anti-tumor effects in multiple early/primary tumor models (GBM, HCC, UCA and ovarian) and modest benefit in PDAC
- Mouse models use same chamber and antisense as human studies
- Well-tolerated, as in the clinic
- Immune response correlates across indications, including tumor antigen-specific IFN $\gamma$
- Increased activation markers in PBMCs exposed to IGV-001:
  - Increased Dendritic (antigen presenting) Cell activation and T cell memory markers

Exploring combination potential in multiple indications



### Imvax pipeline: Focused on solid tumor types

		Target Validation	IND-enabling	Phase 1	Phase 2	Phase 3
Glioblastoma	IGV-001					Phase 2b underway
Endometrial Cancer	IEC-001			IND filing	g in 2023	
Hepatocellular Carcinoma	IHC-001					
Urothelial Carcinoma	IUC-001					
Ovarian Cancer	IOC-001					



### A compelling immuno-oncology platform opportunity

- The Imvax Goldspire<sup>™</sup> platform harnesses decades of research and multiple validated technologies to create a pipeline of personalized, whole tumor-derived treatments targeting intractable solid tumors
- Lead asset to treat newly-diagnosed GBM currently in Phase 2b
- Additional IND planned for endometrial cancer in 2023
- Established GMP manufacturing capabilities at Imvax
- Projected up to \$6B annual revenue in addressable markets, largely underserved therapeutic areas (on a non-risk adjusted basis)
  - \$2B \$3B global peak sales in ndGBM alone
- Seasoned leadership with deep biopharma development and commercialization experience







#### 601 Walnut Street, Suite 440 W • Philadelphia, PA • 19106

imvax.com